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(54) **FECAL COLLECTION SYSTEMS AND METHODS**

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See application file for complete search history.

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Primary Examiner — Susan S Su

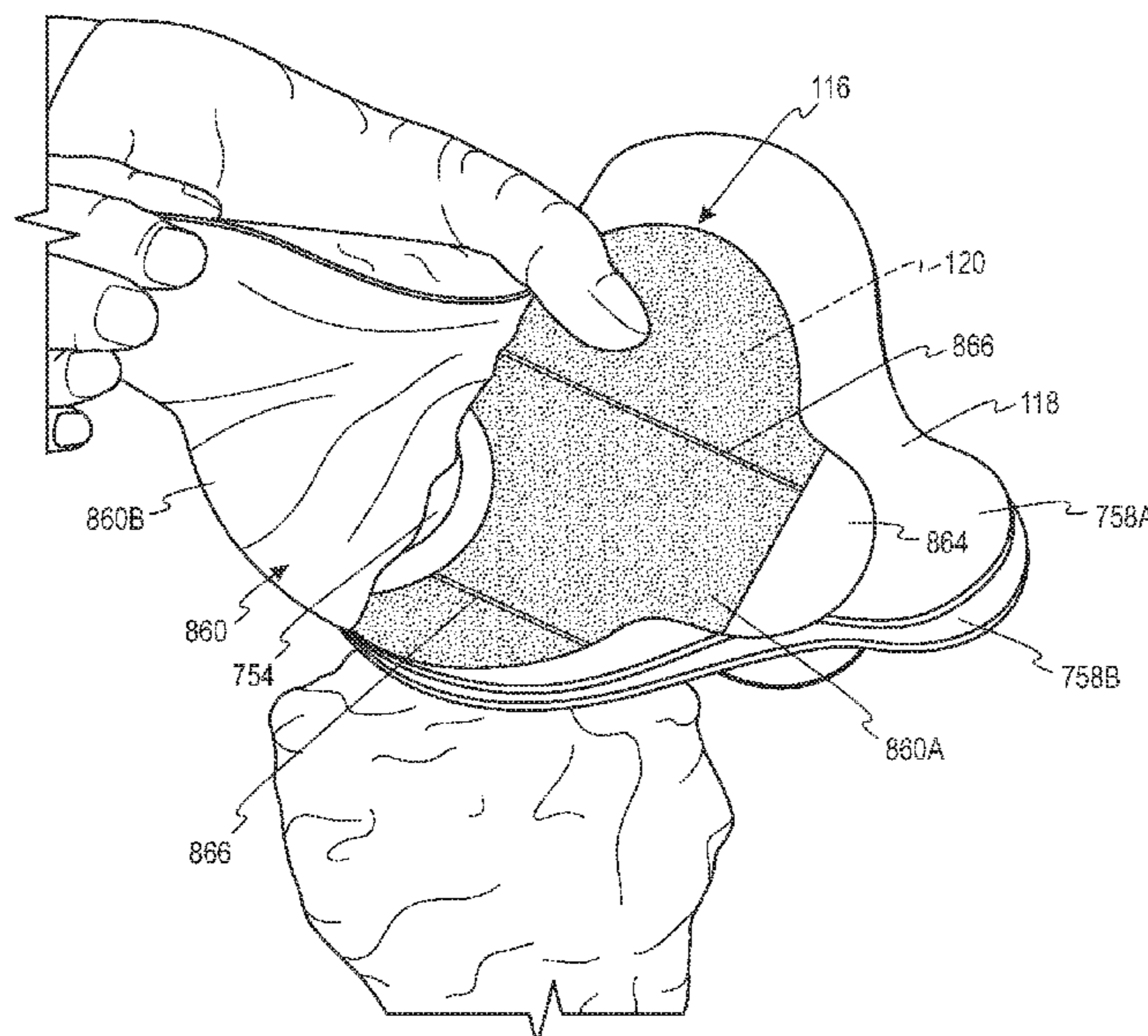
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(57) **ABSTRACT**

In an example, a fecal collection system includes a user interface assembly, a drainage conduit, and a collection reservoir. The user interface assembly includes a user interface and an applicator. The user interface has a proximal side and a distal side. The proximal side is configured to couple to skin of a user. The applicator is coupled to the distal side of the user interface. The applicator is removable from the user interface while the user interface is coupled to the user. The drainage conduit extends between a proximal end and a distal end. The proximal end is configured to couple to the distal side of the user interface. The drainage conduit defines a lumen configured to guide feces from the proximal end to the distal end. The collection reservoir coupled to the distal end of the drainage conduit.

20 Claims, 26 Drawing Sheets



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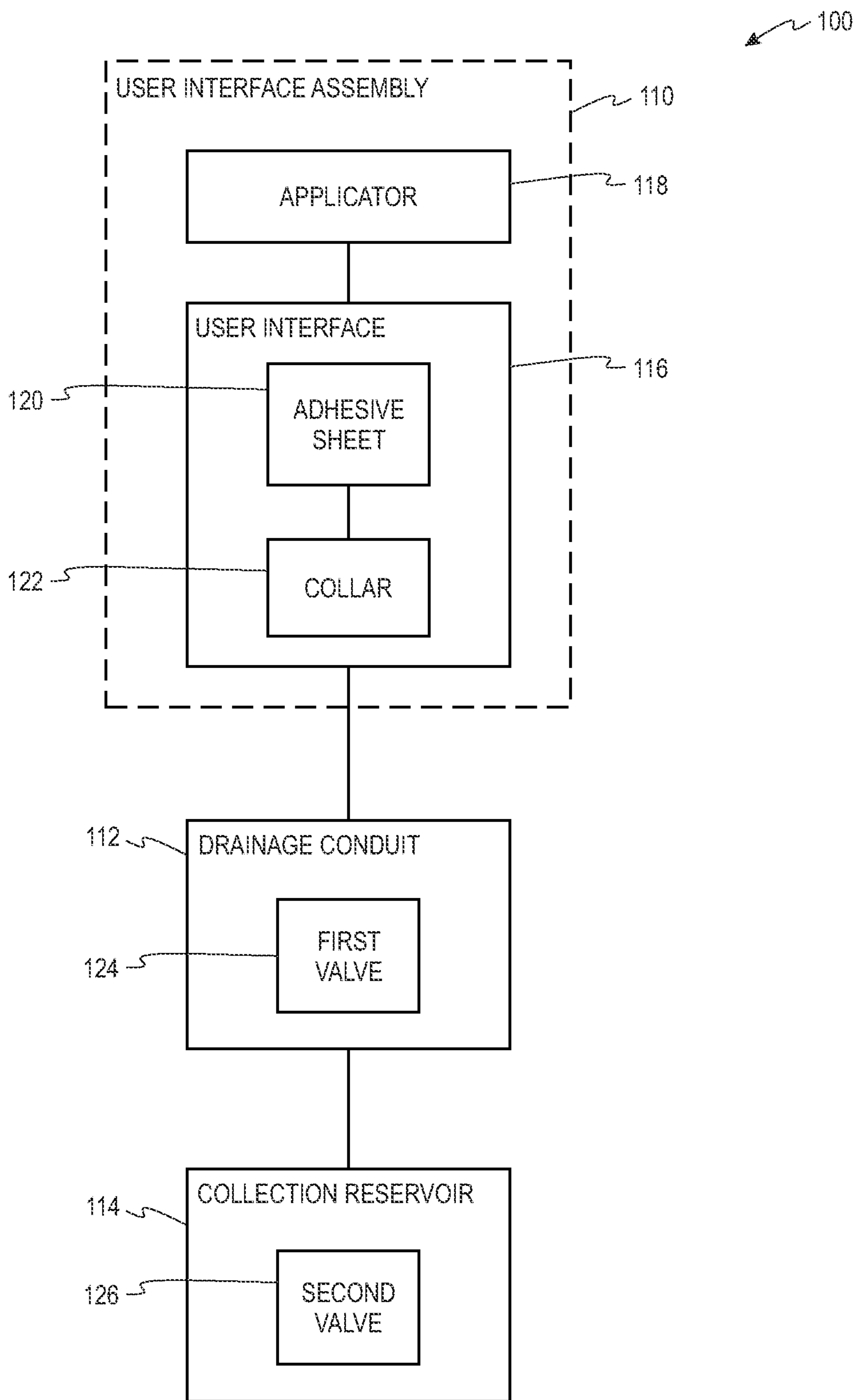


Fig. 1

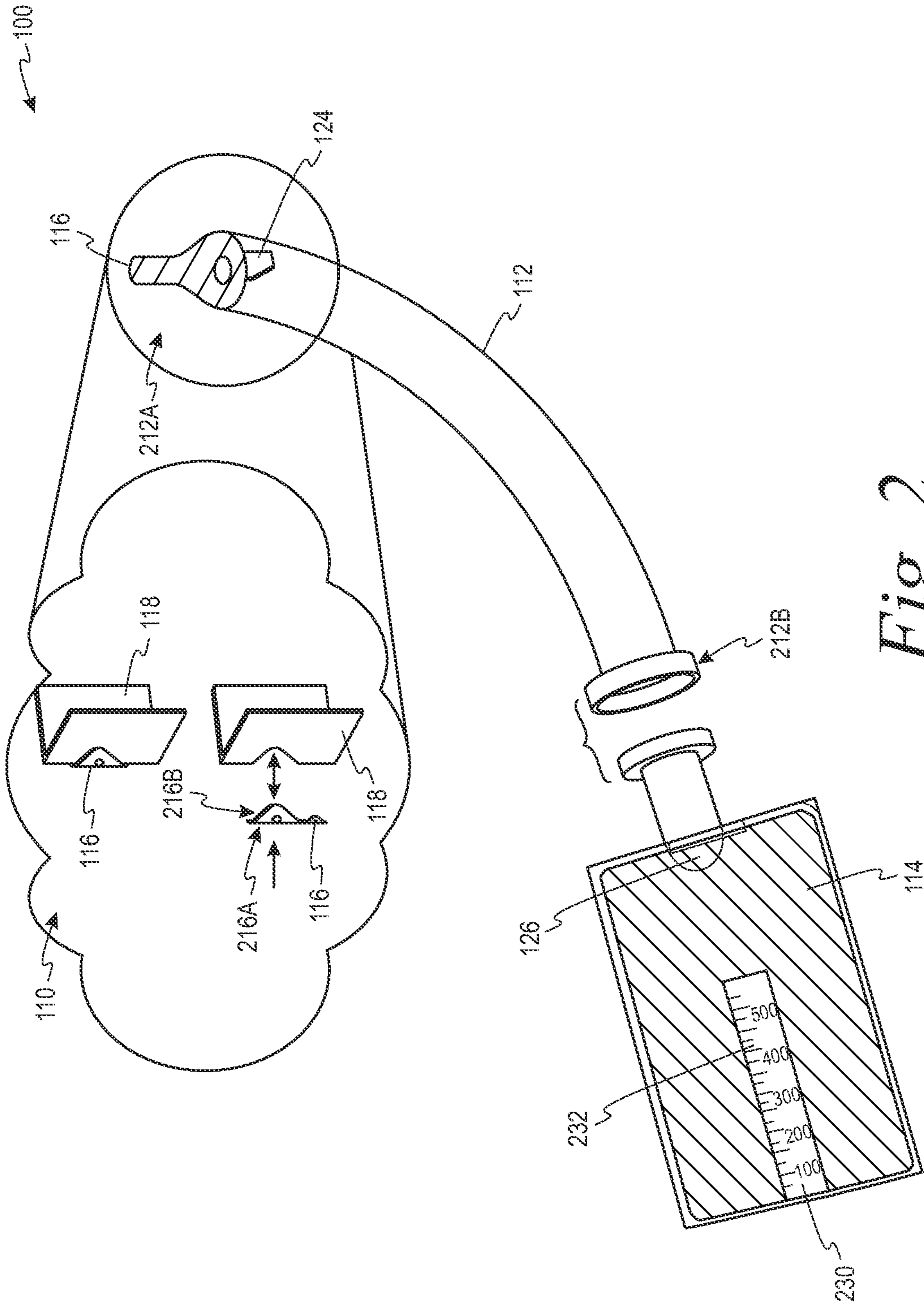


Fig. 2

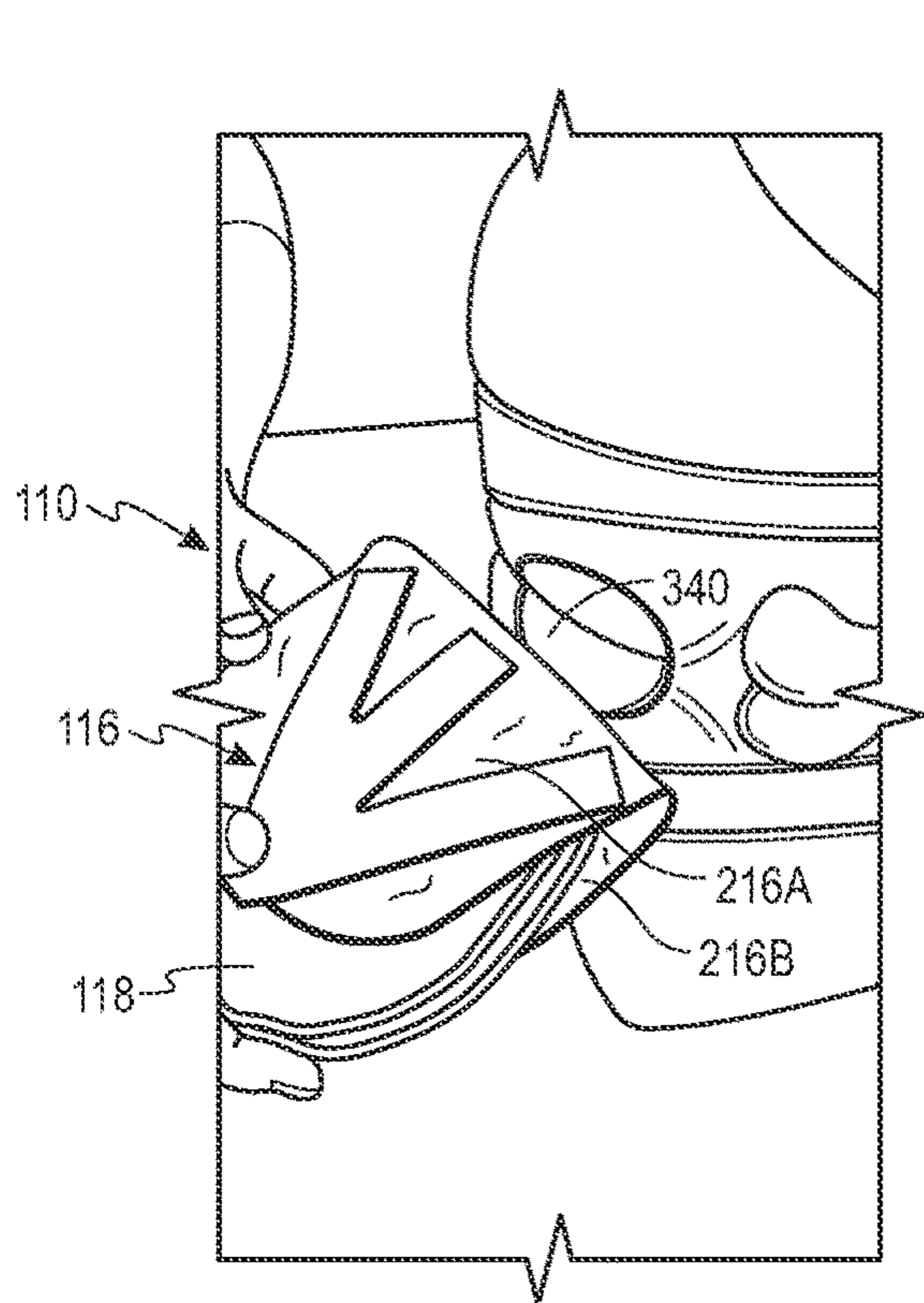


Fig. 3A

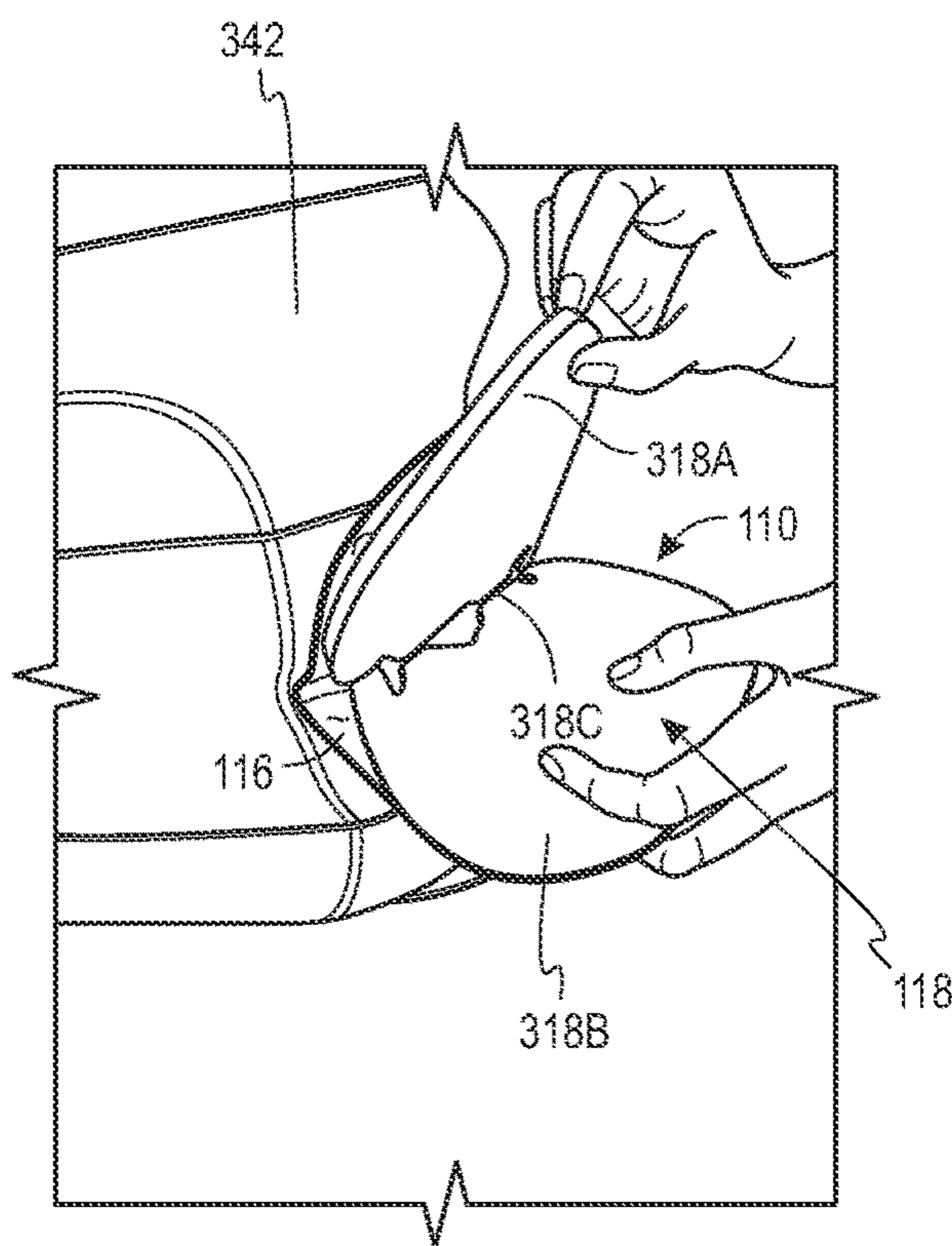


Fig. 3B

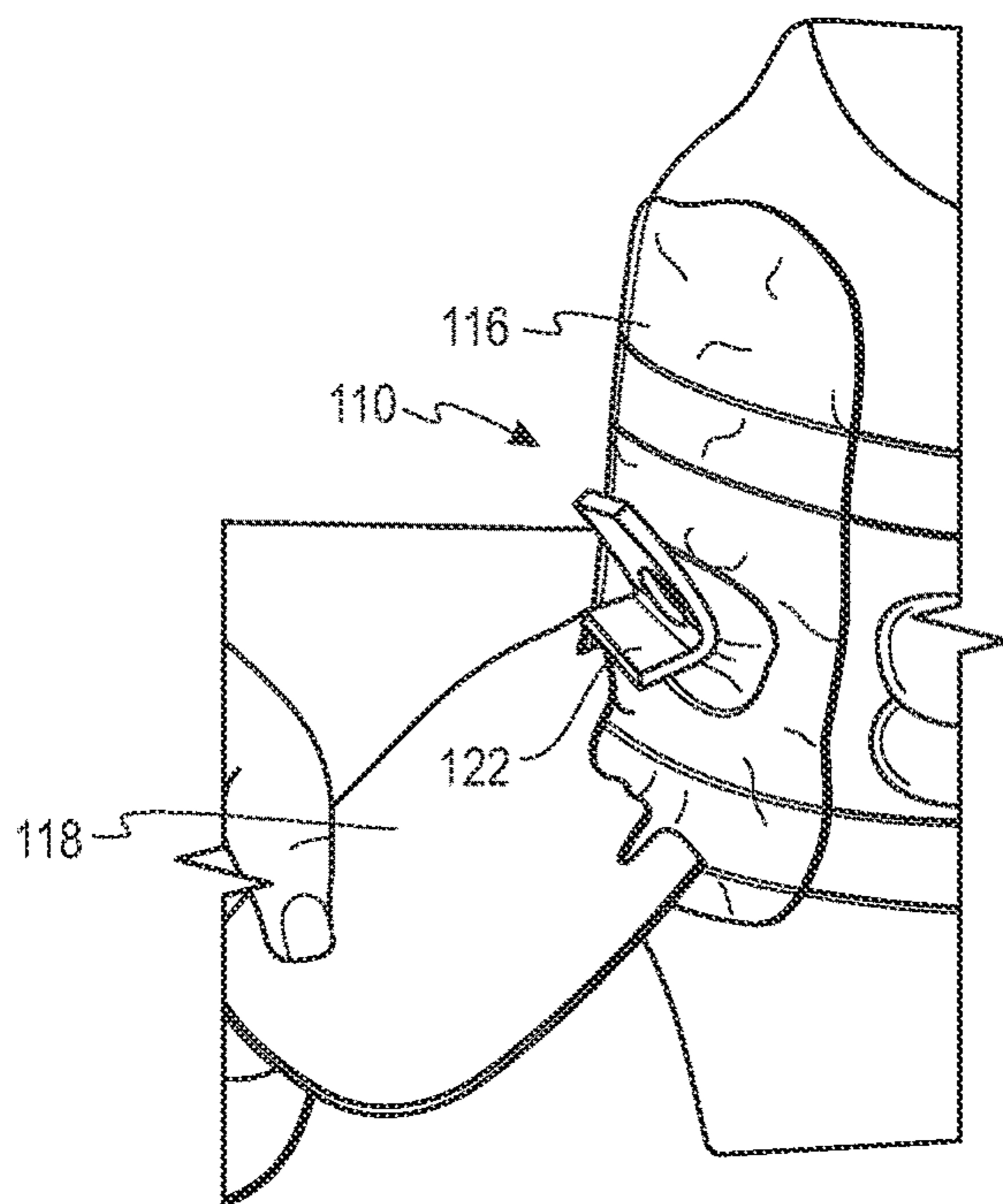


Fig. 3C

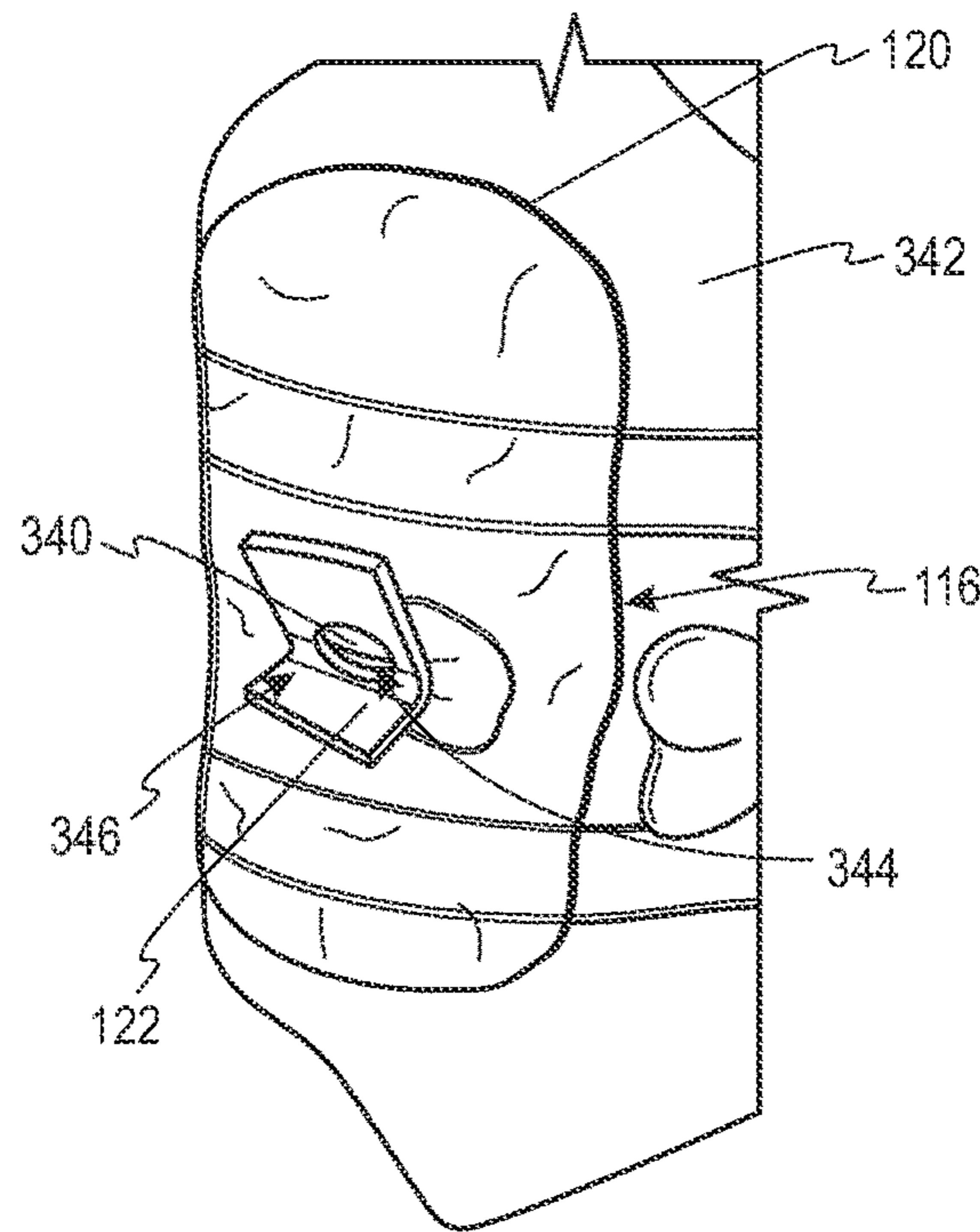


Fig. 3D

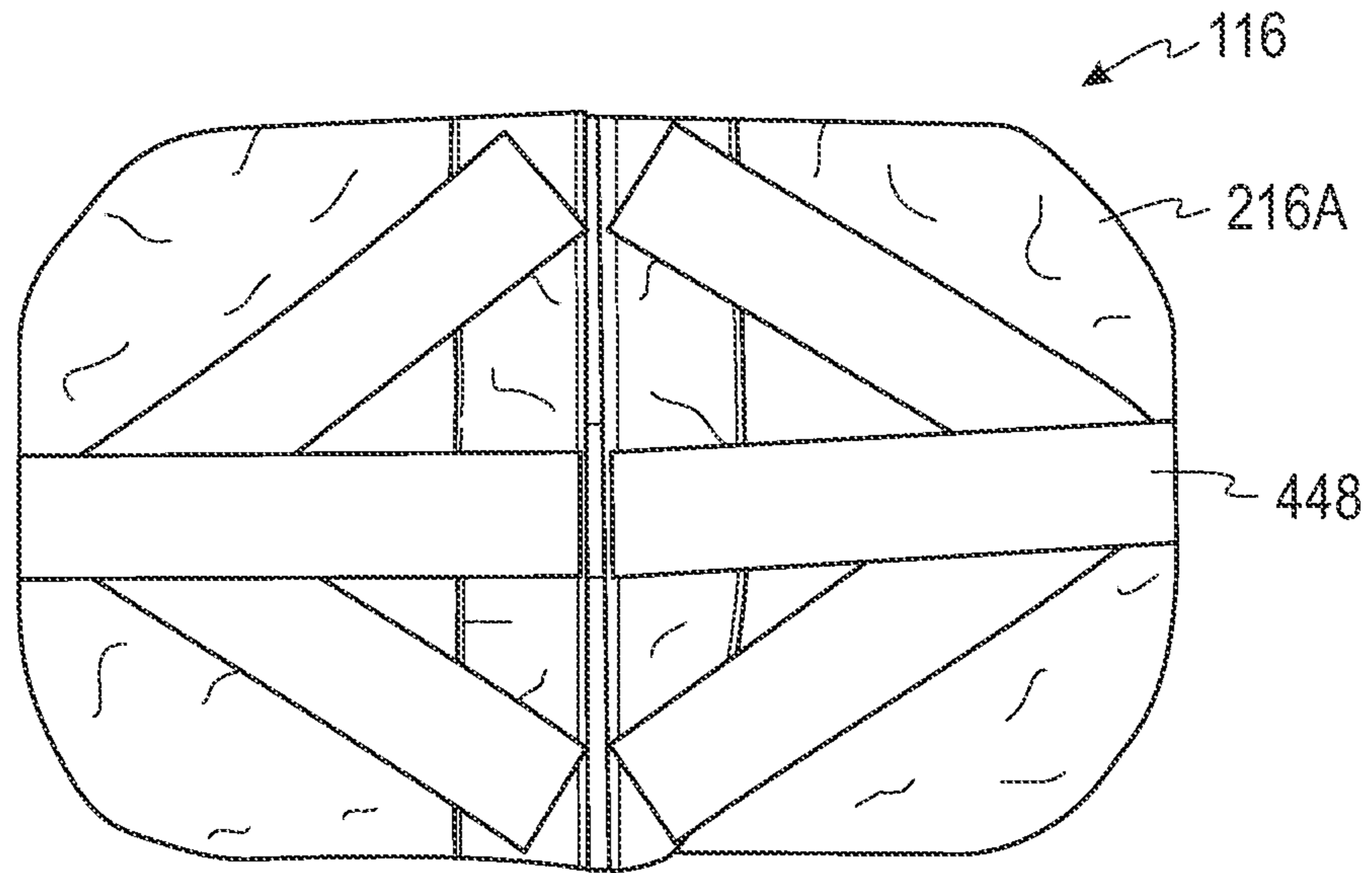


Fig. 4

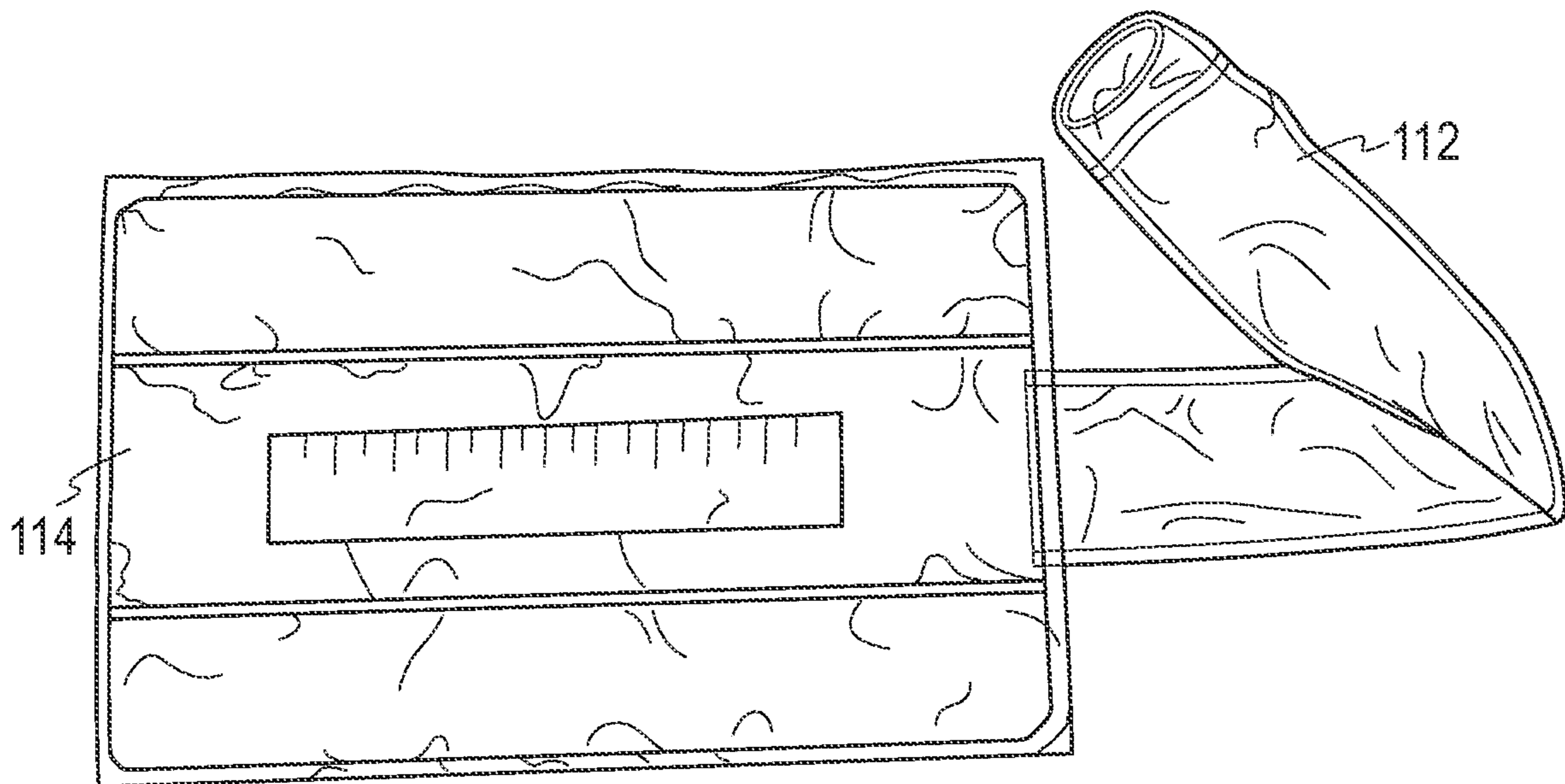


Fig. 5

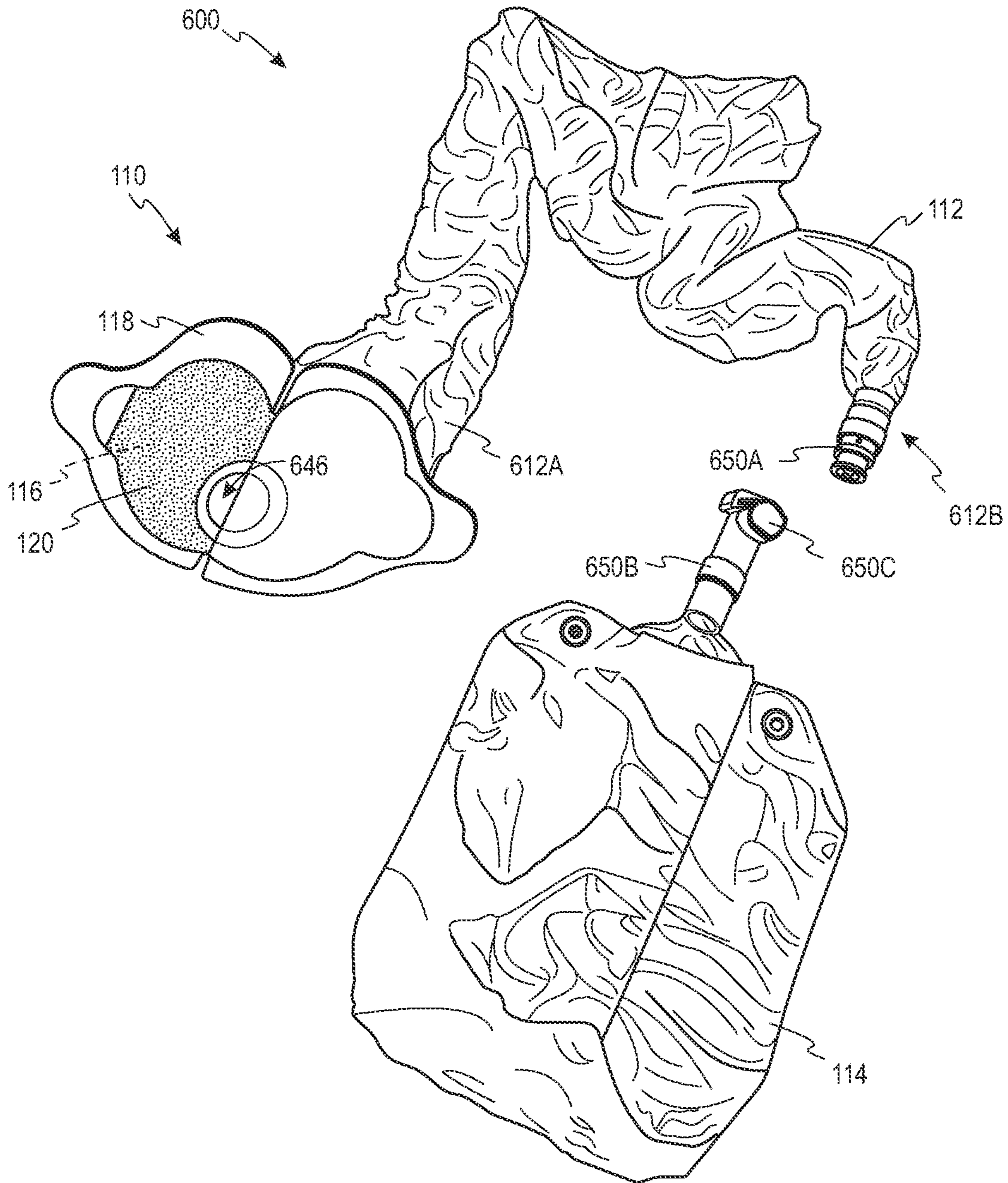


Fig. 6

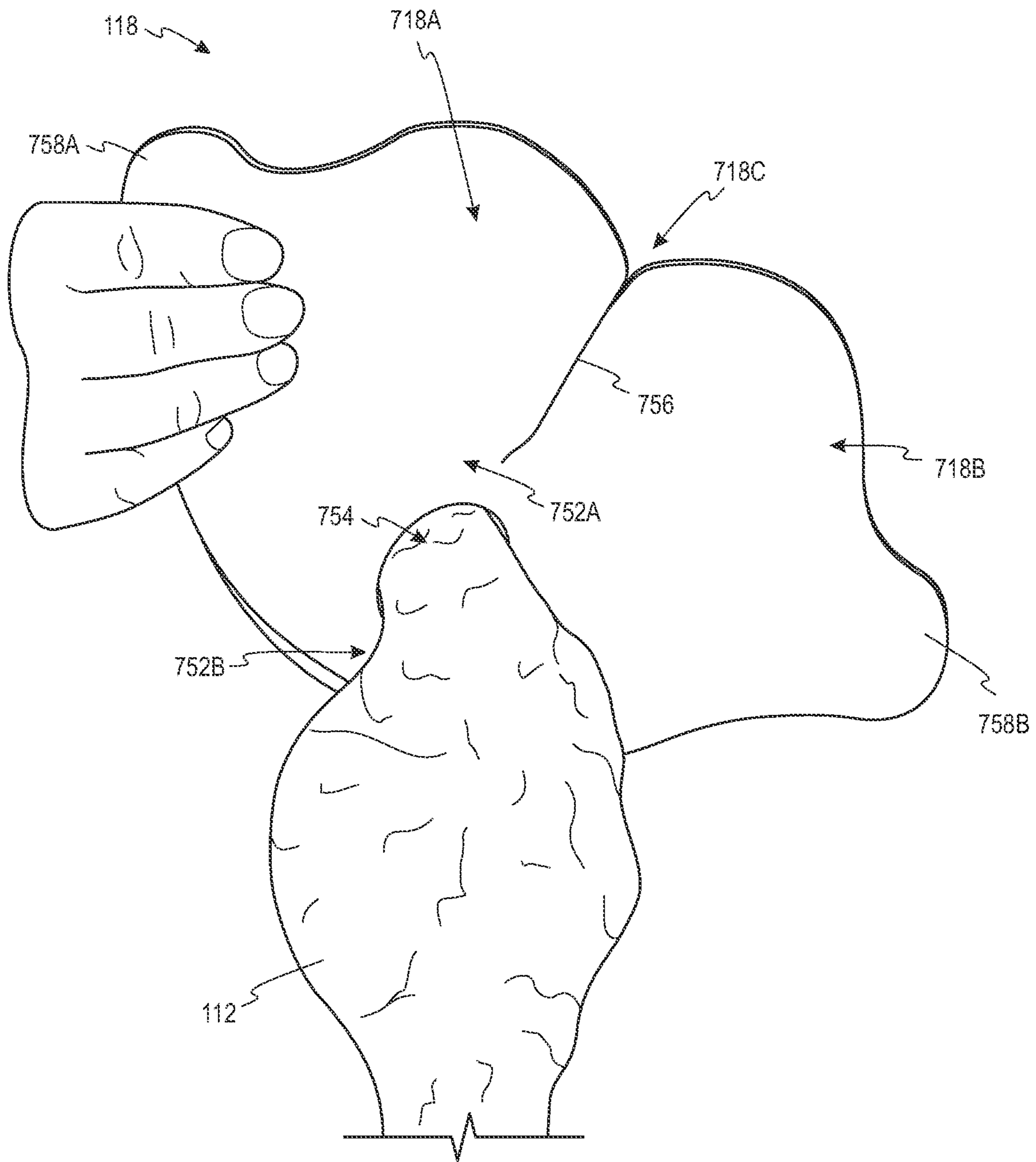


Fig. 7

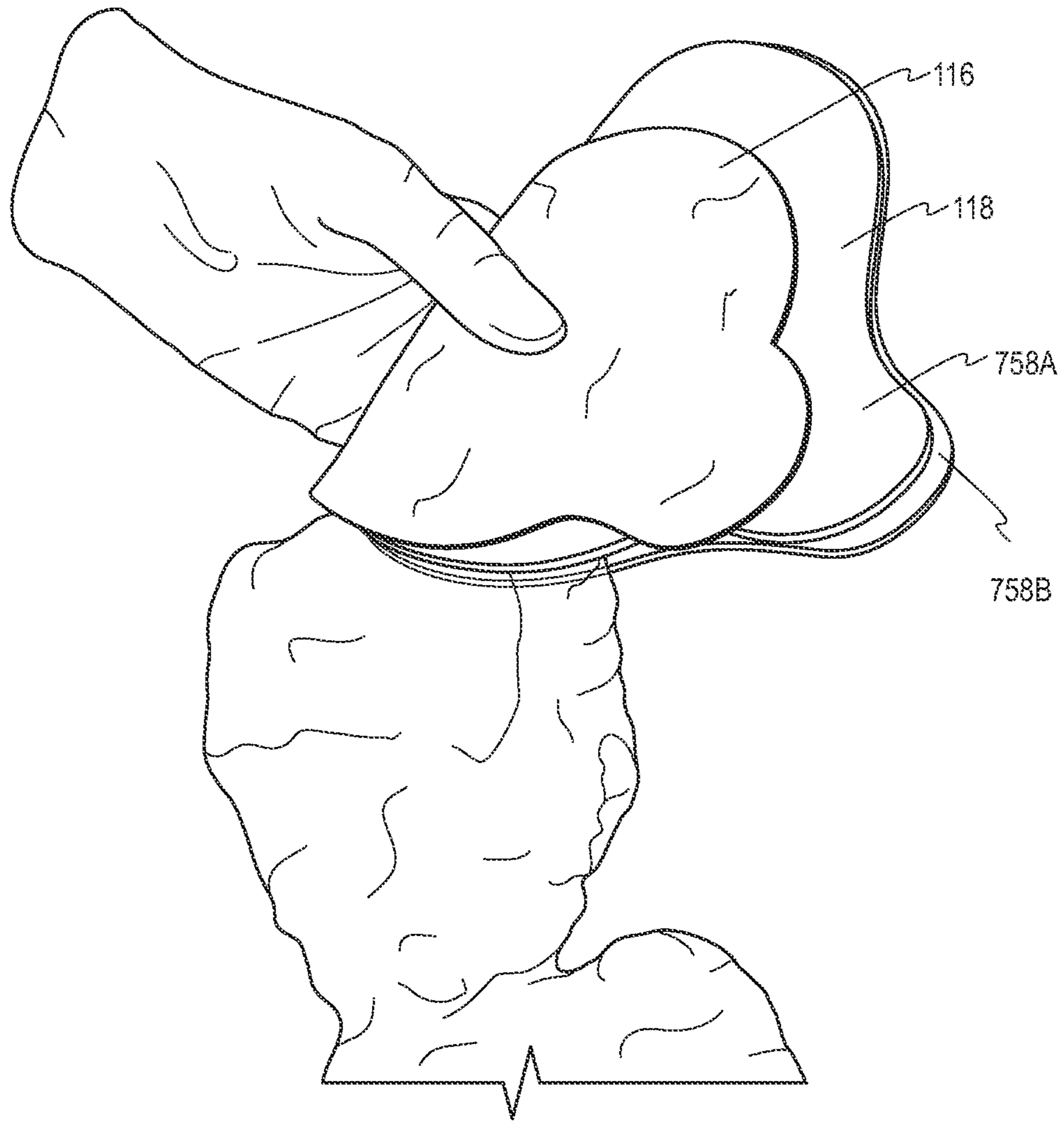


Fig. 8A

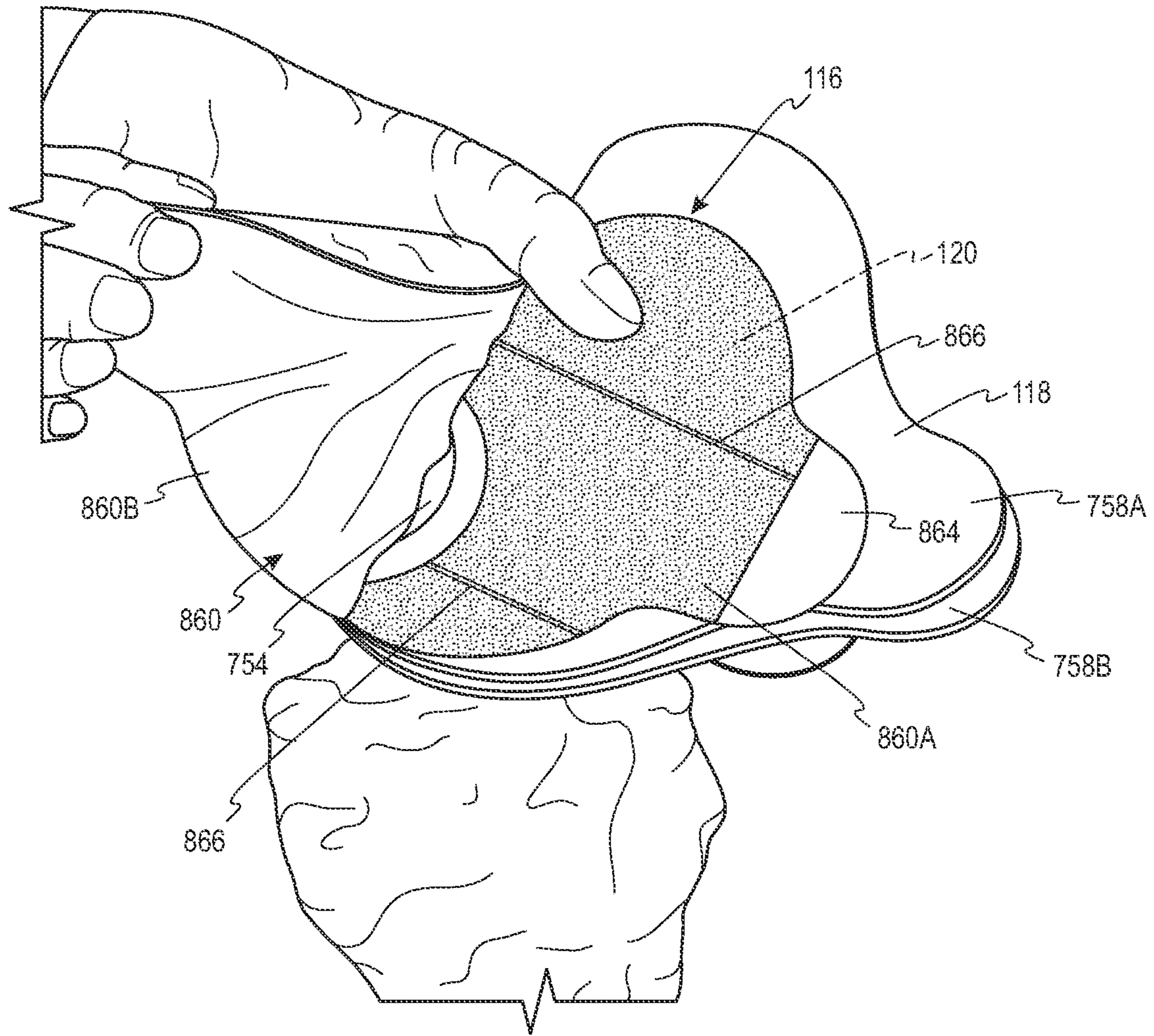


Fig. 8B

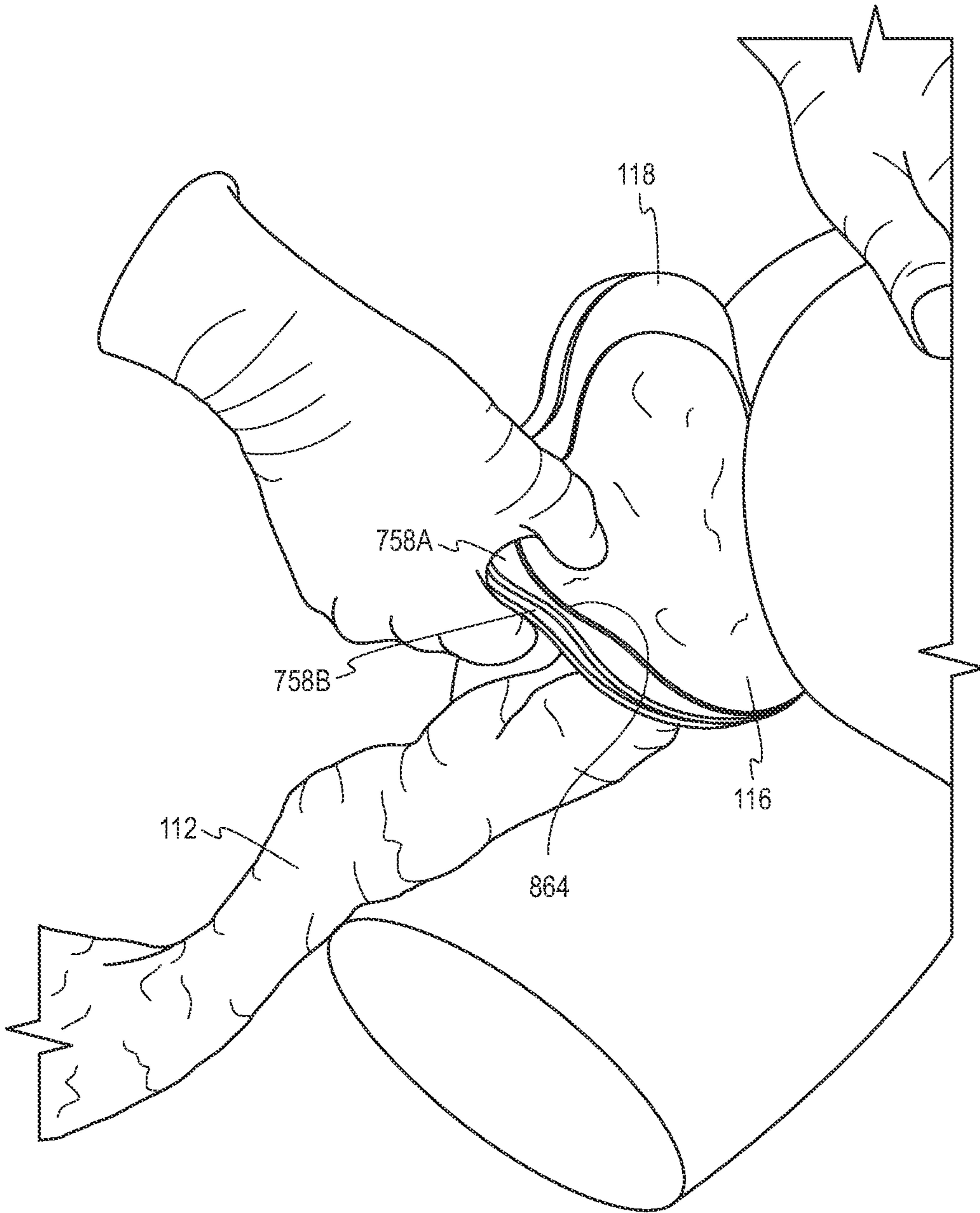


Fig. 9A

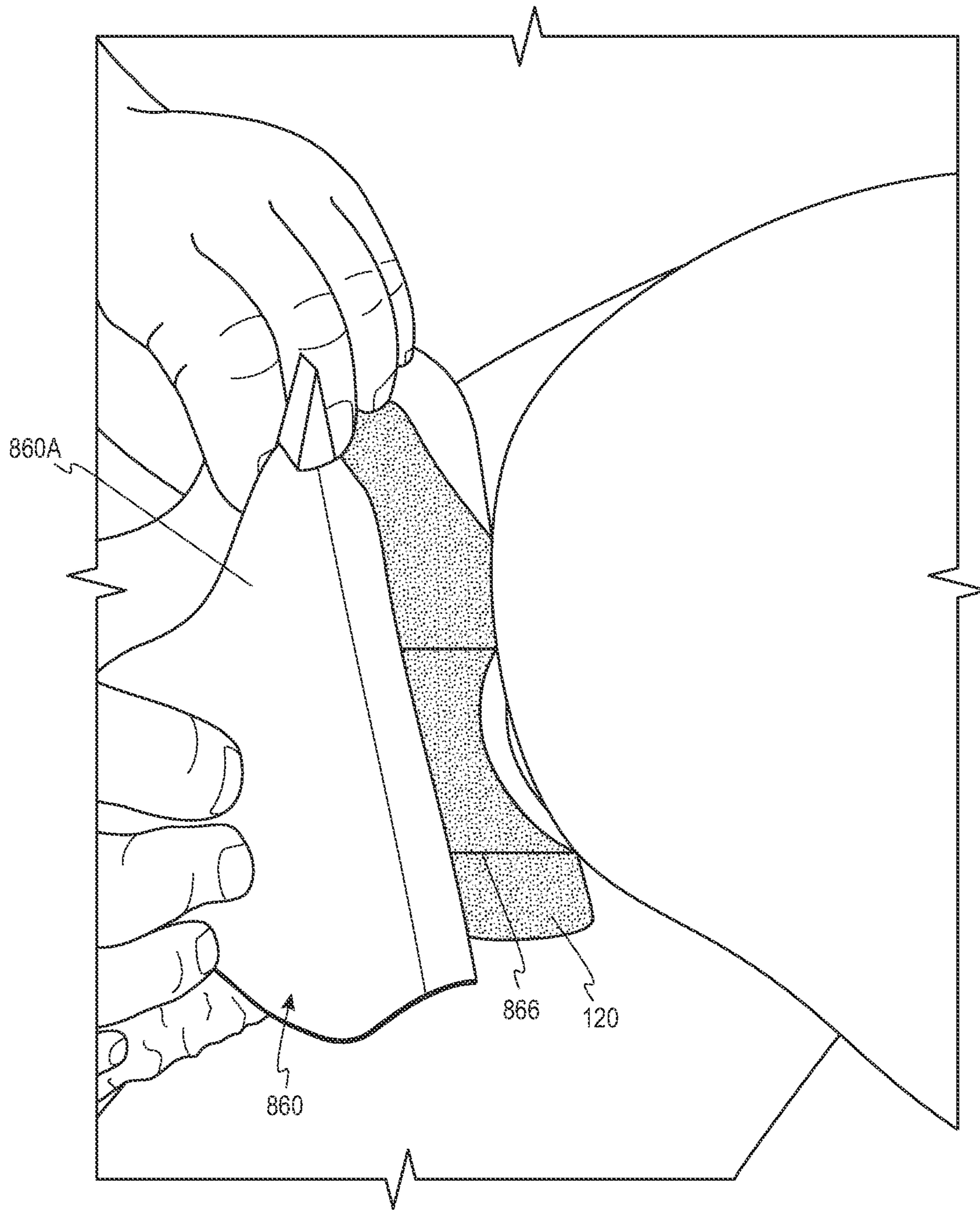


Fig. 9B

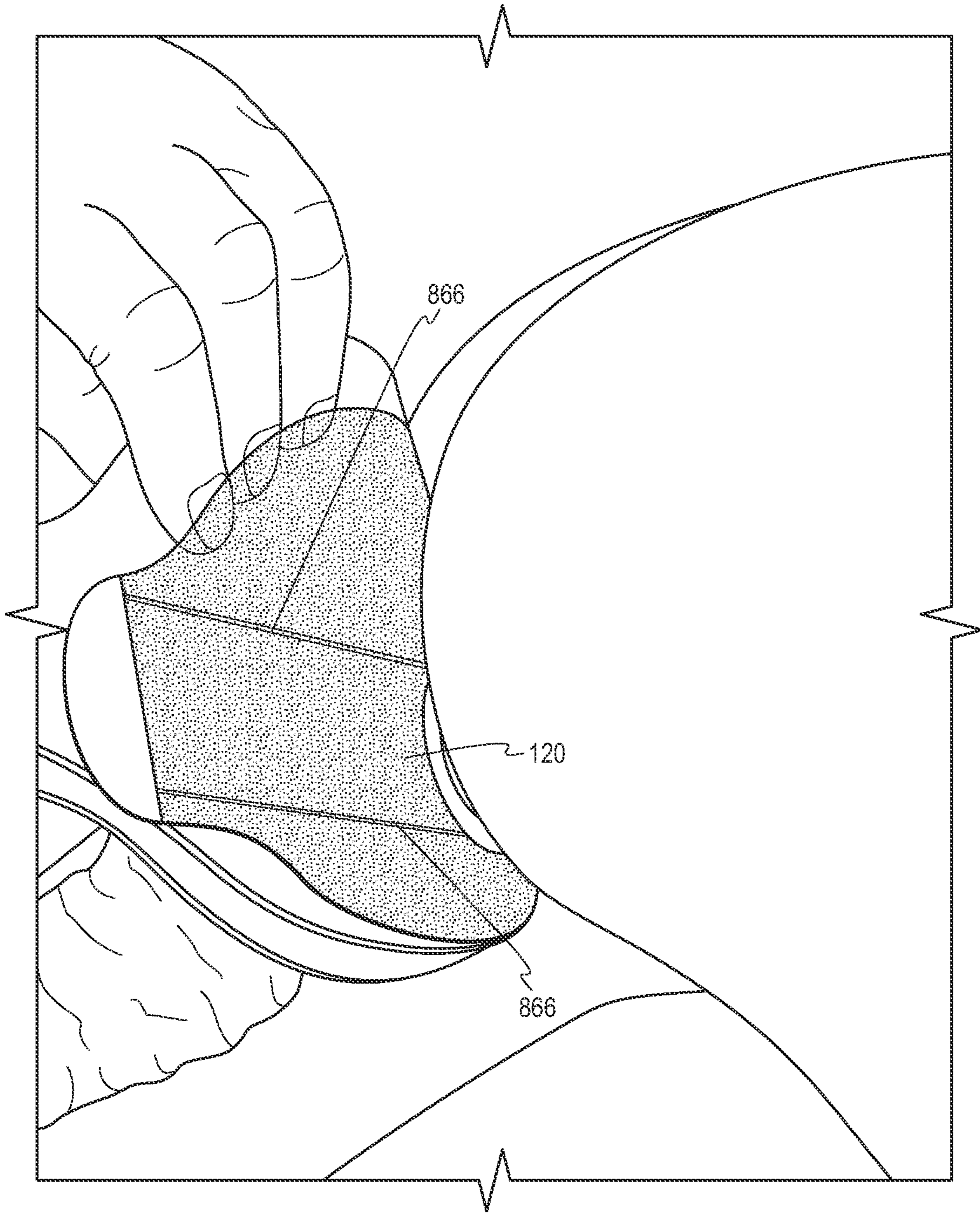


Fig. 9C

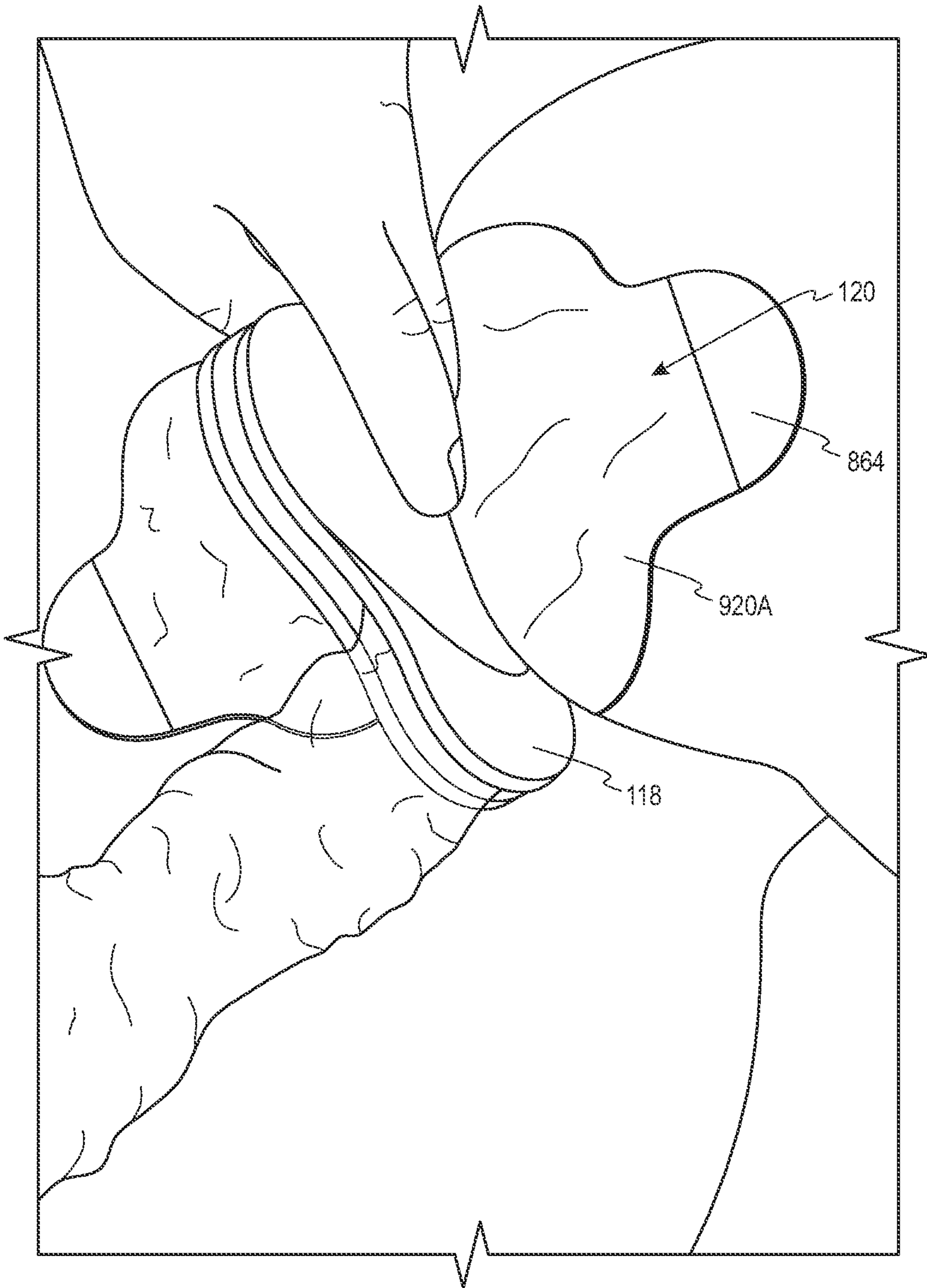


Fig. 9D

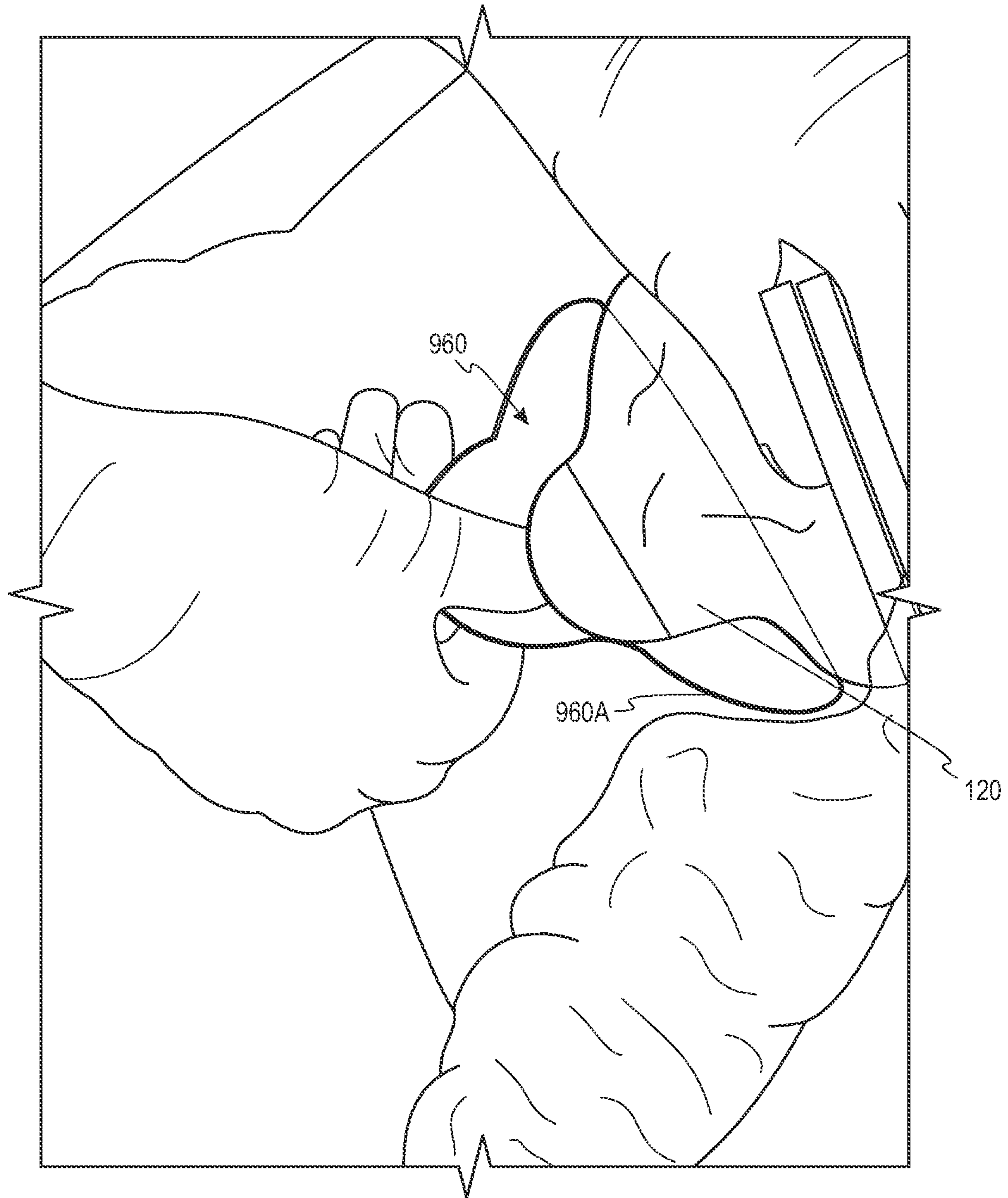


Fig. 9E

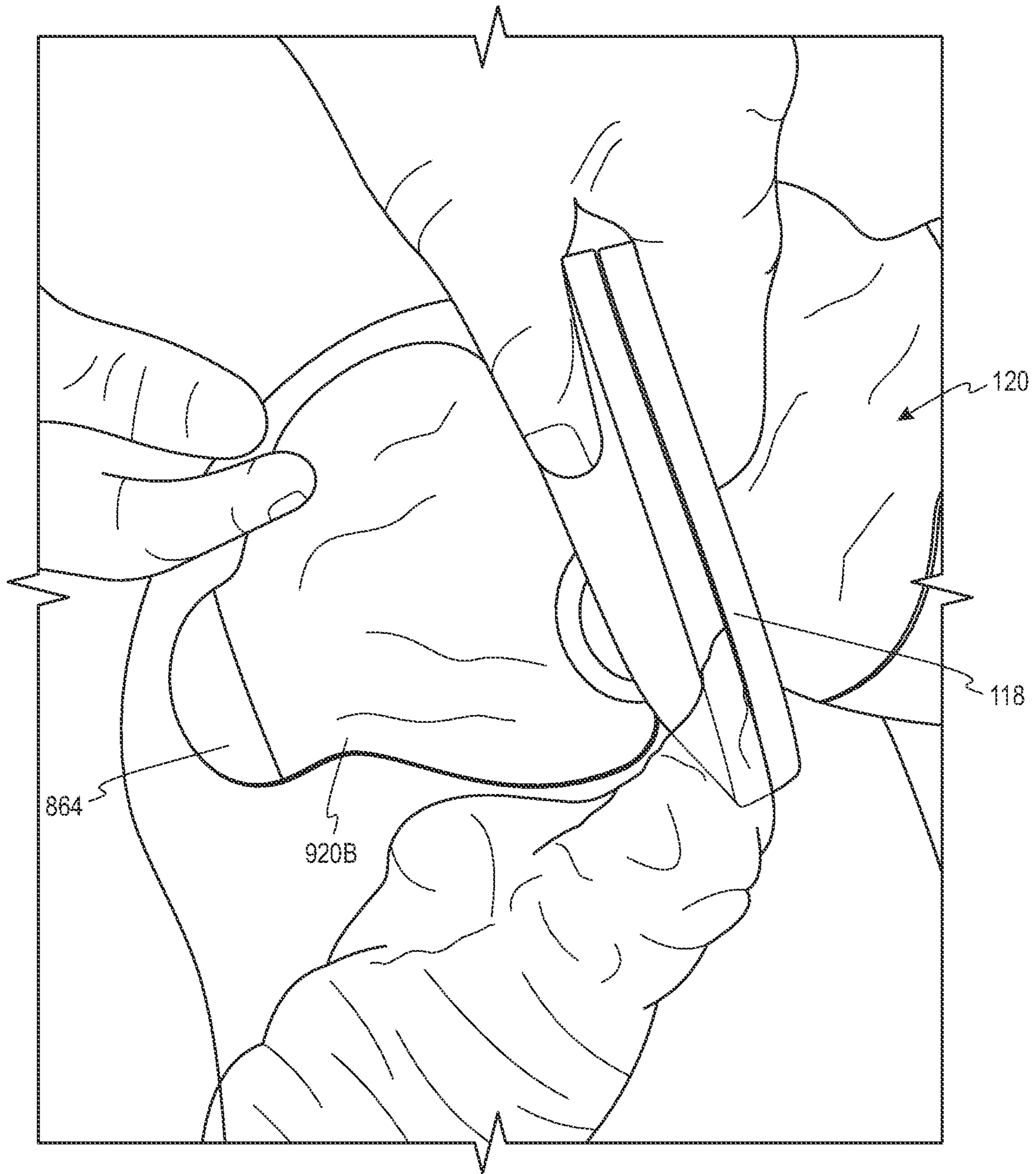


Fig. 9F

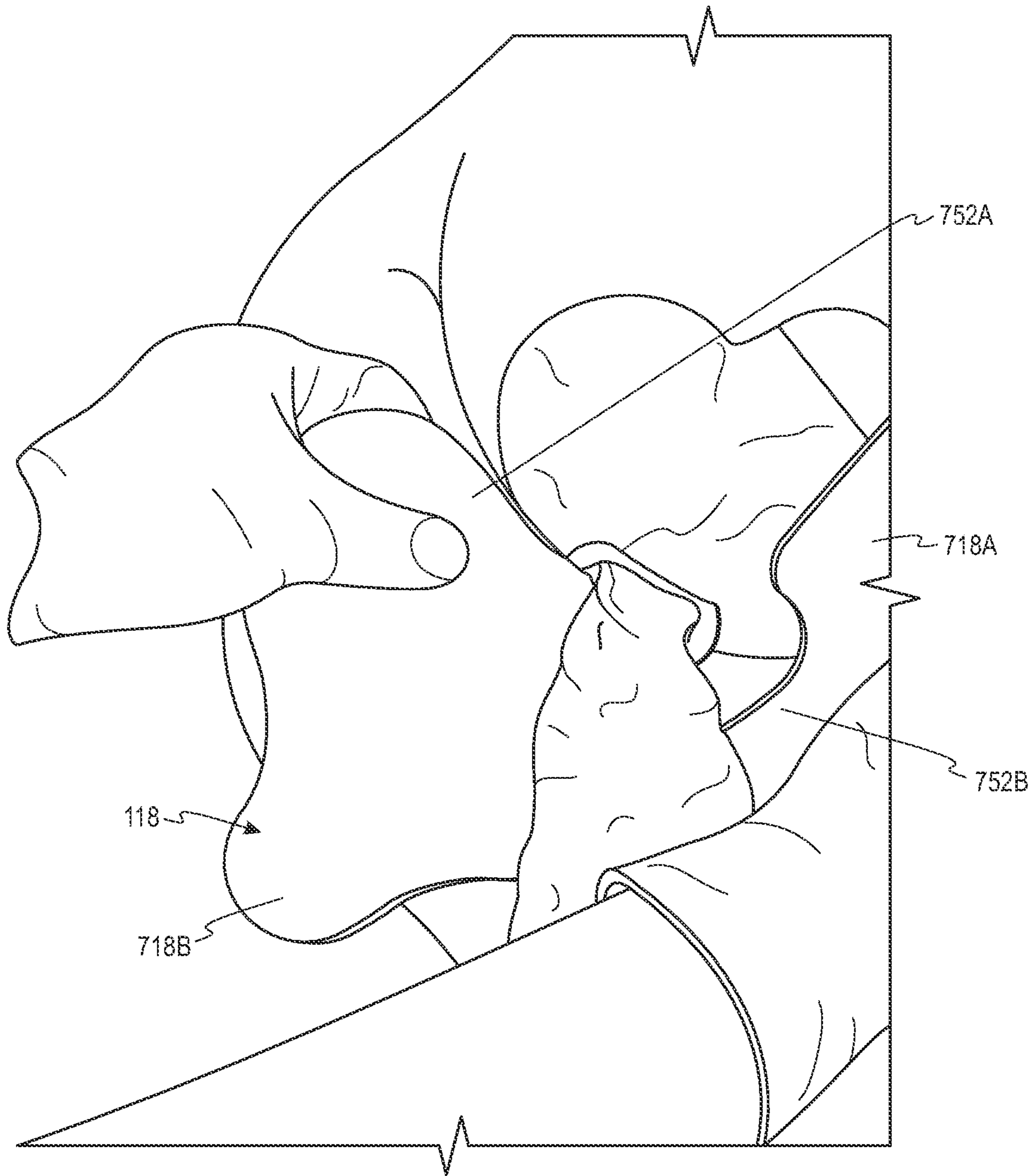


Fig. 9G

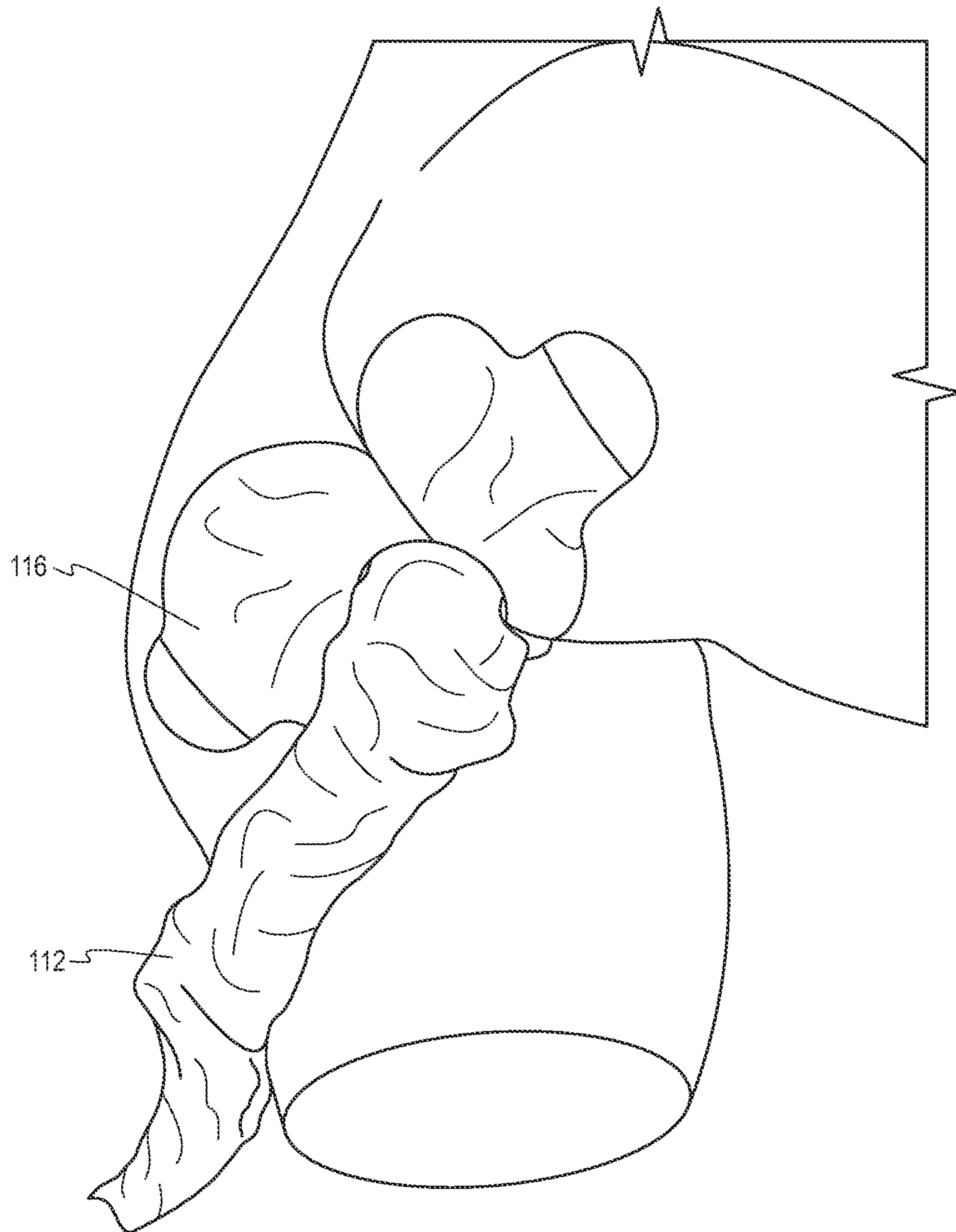


Fig. 9H

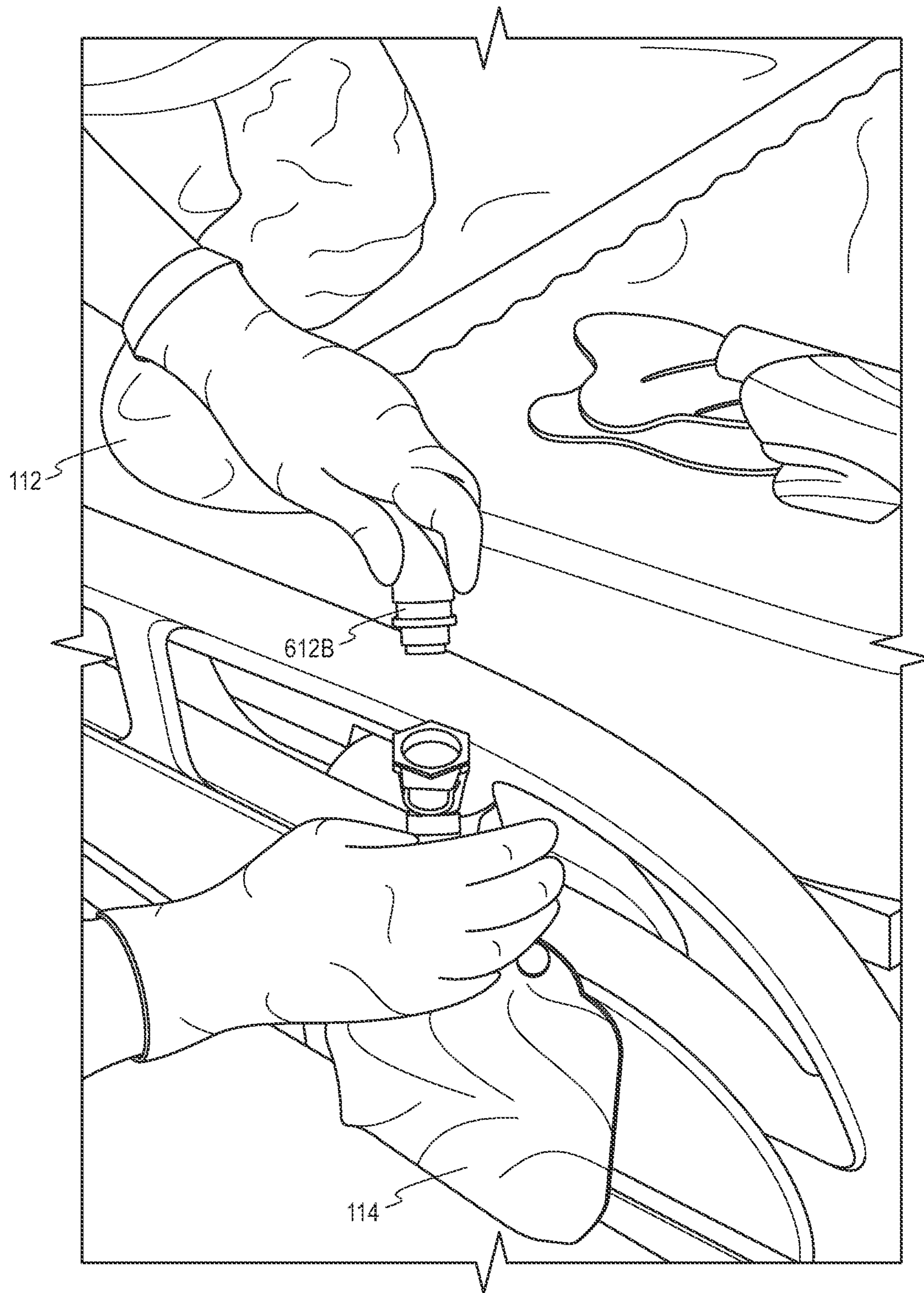


Fig. 9I

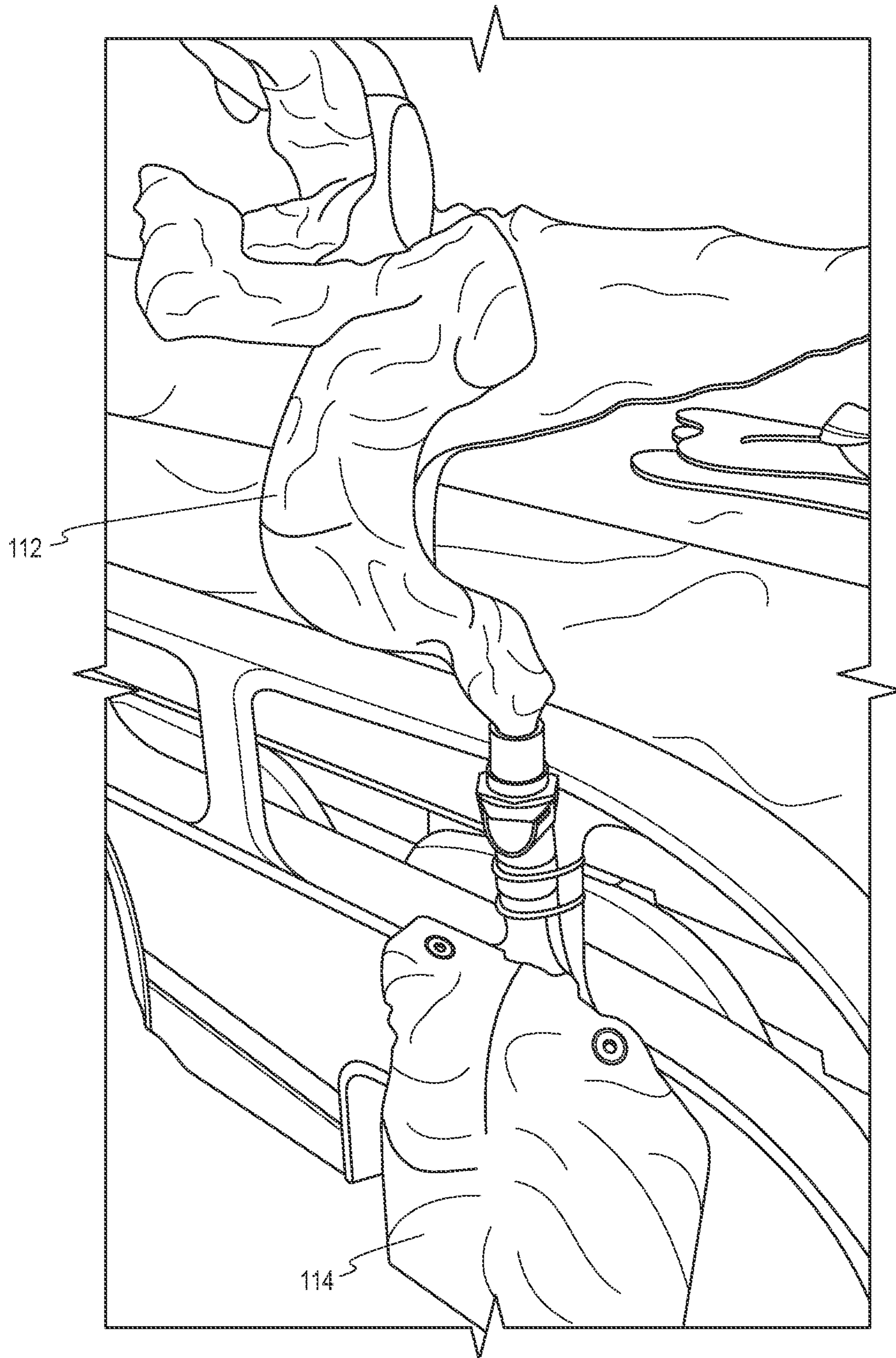


Fig. 9J

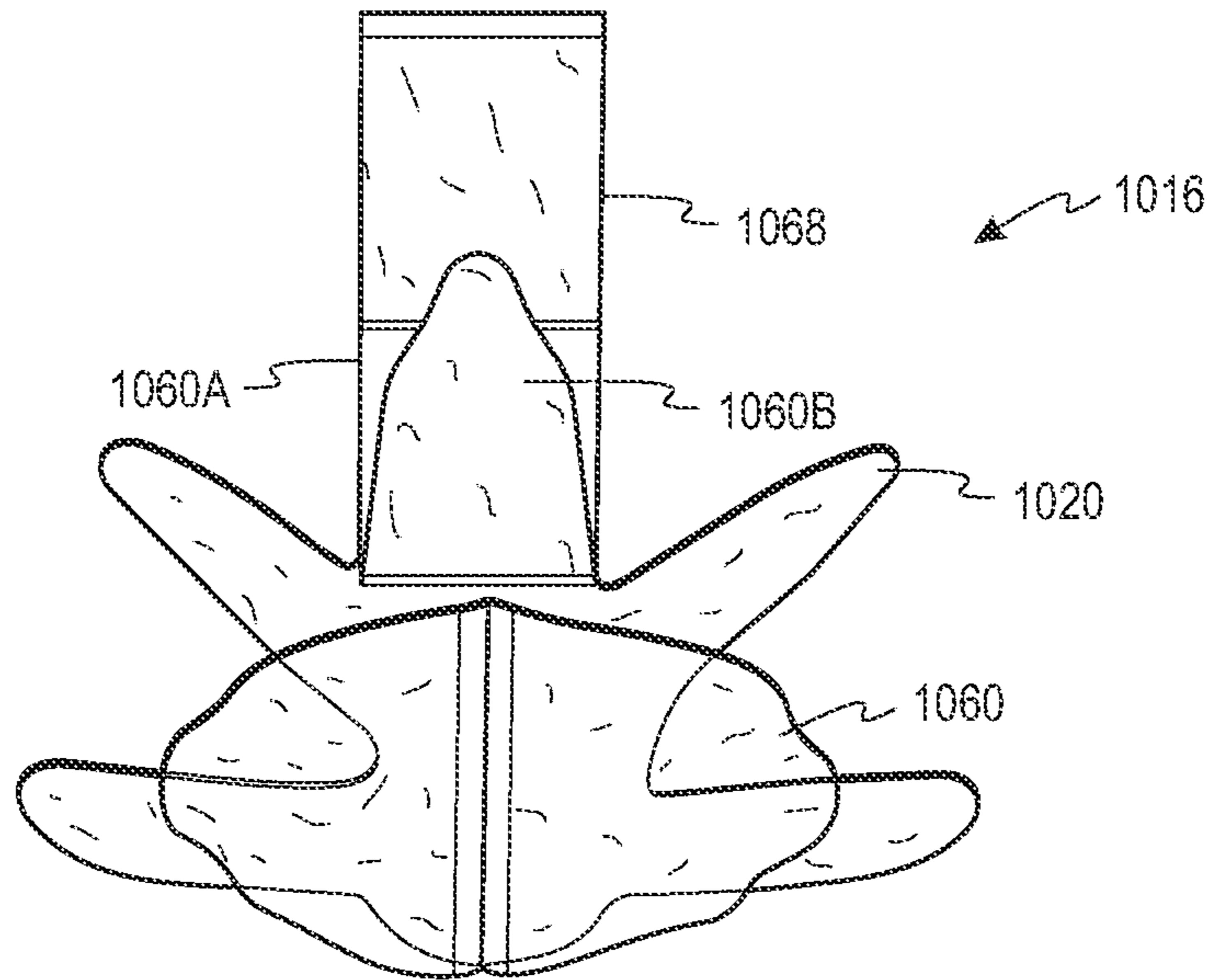


Fig. 10A

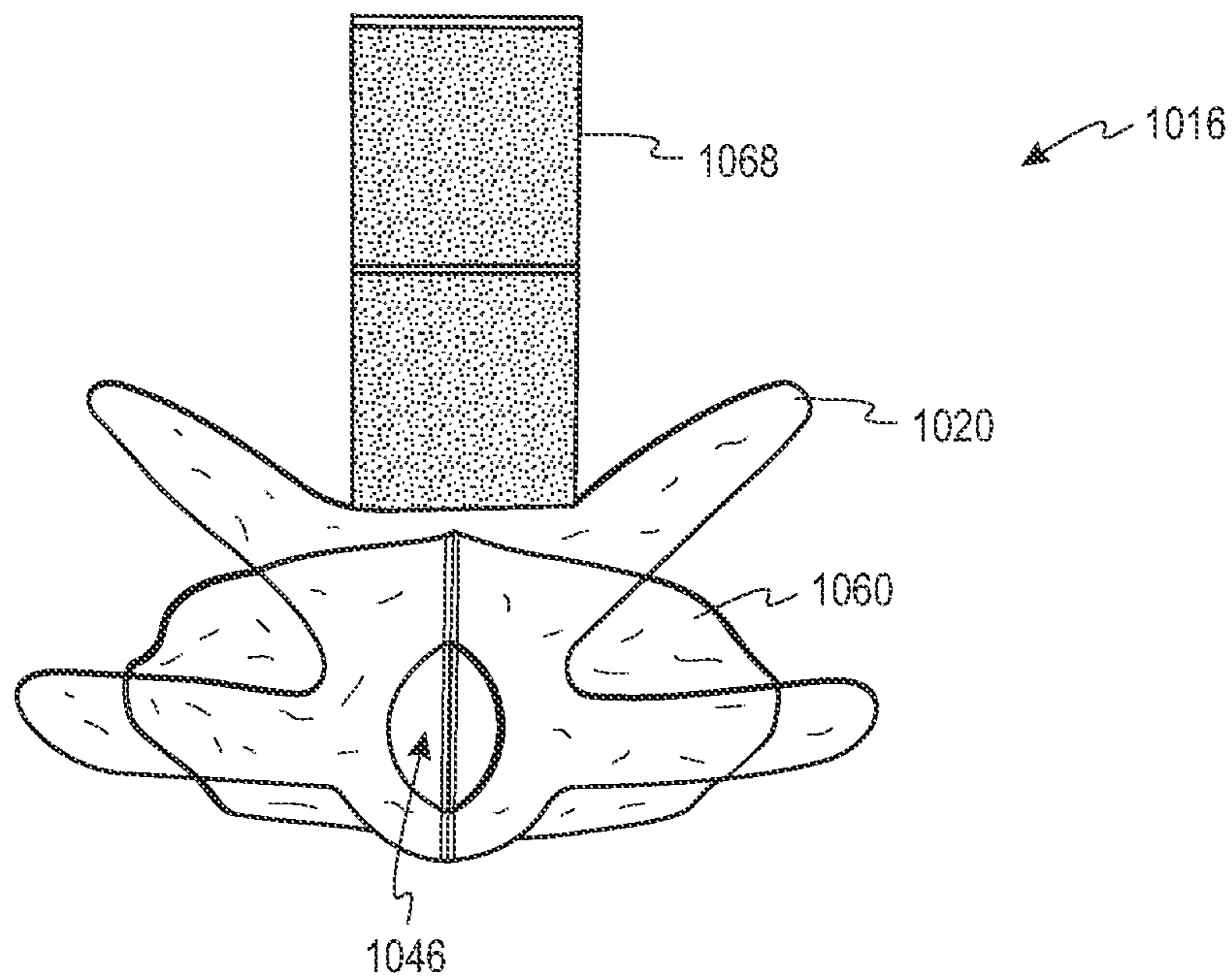


Fig. 10B

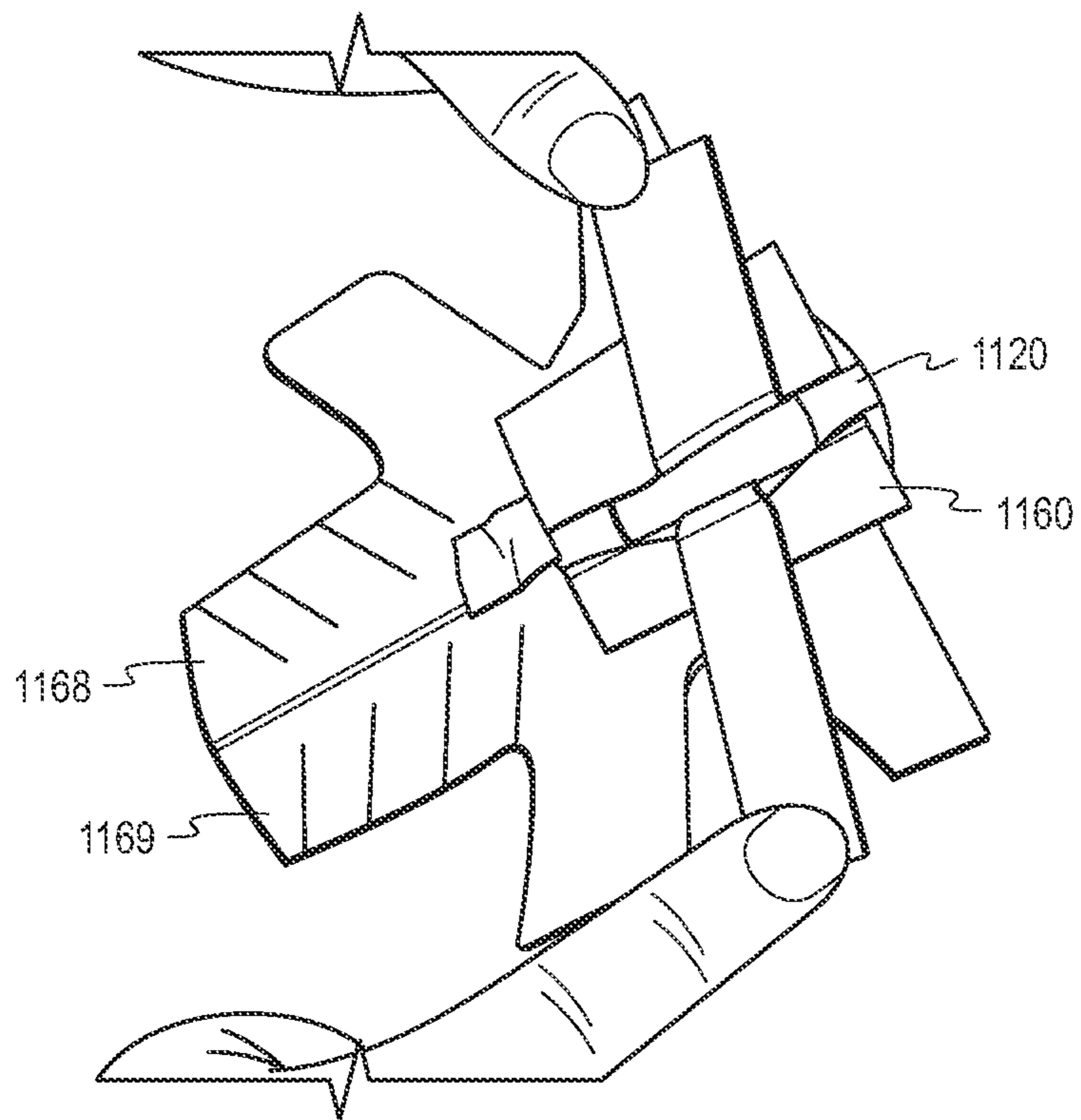


Fig. 11A

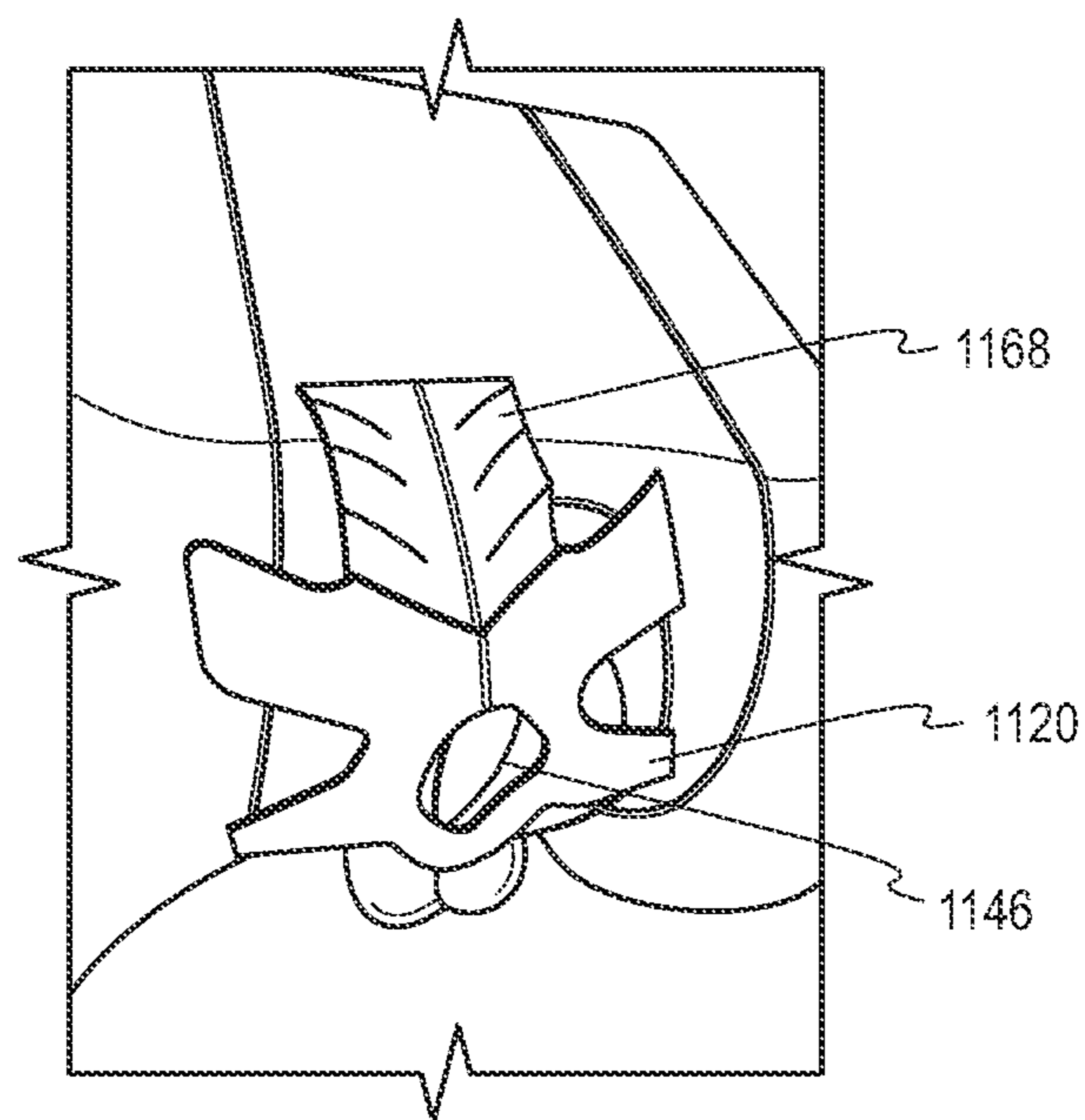


Fig. 11B

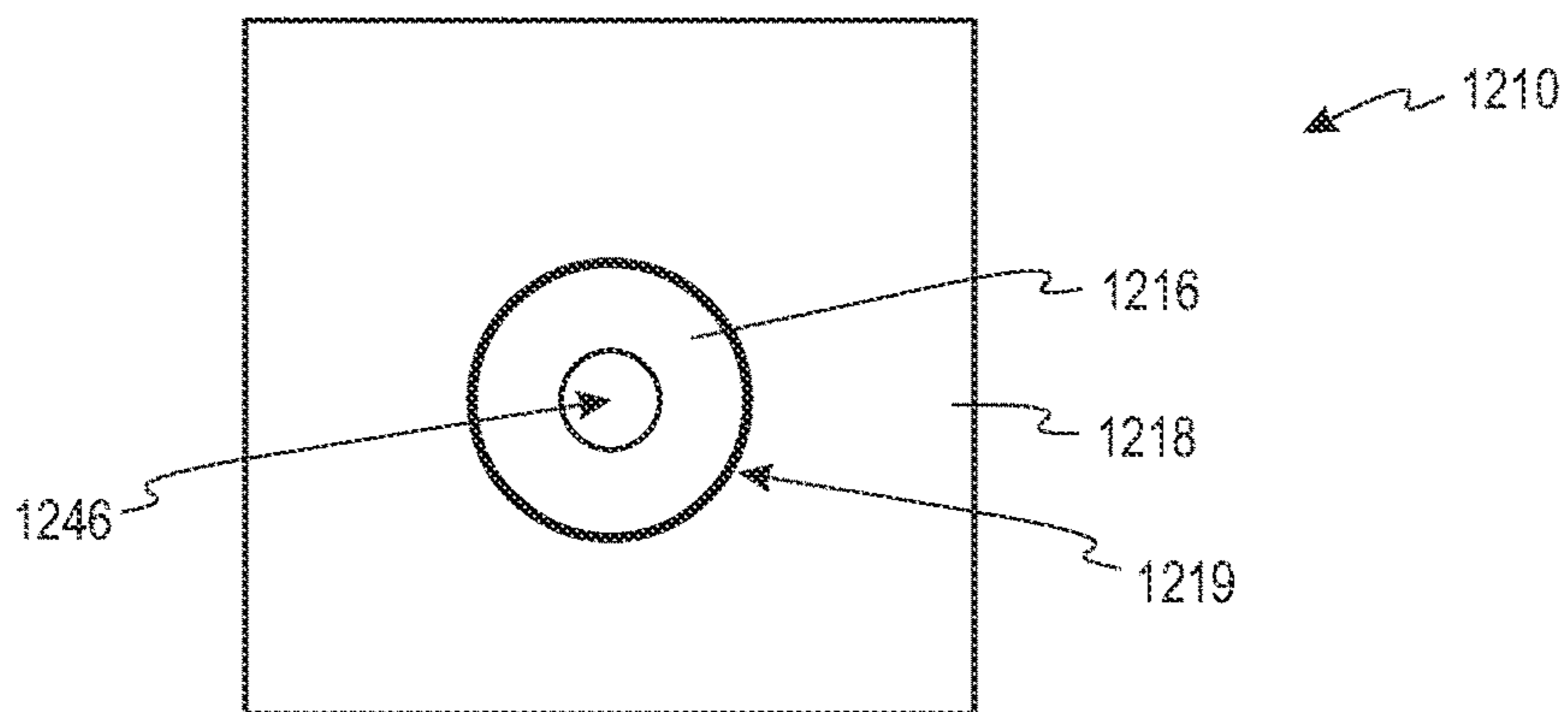


Fig. 12A

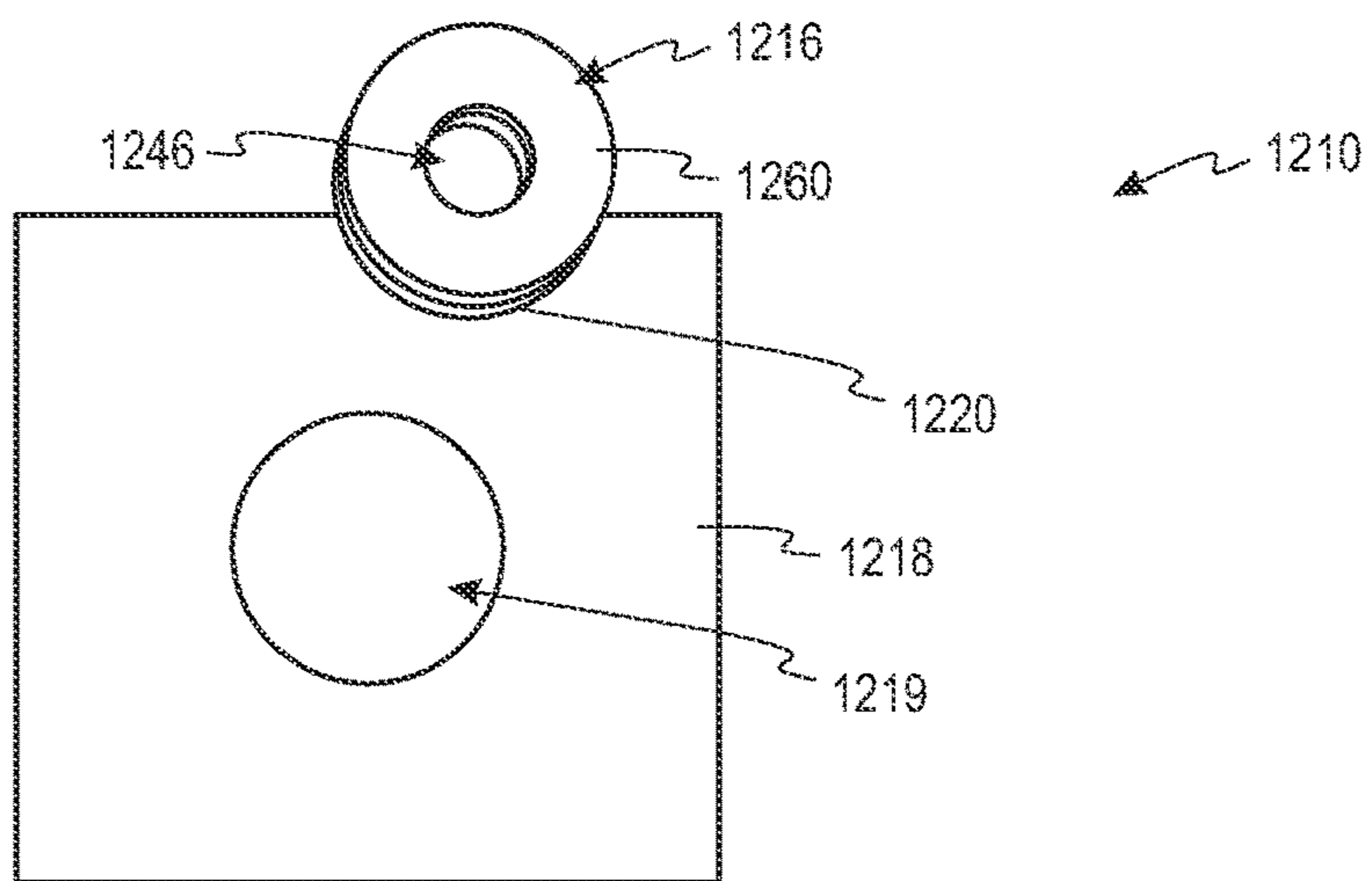


Fig. 12B

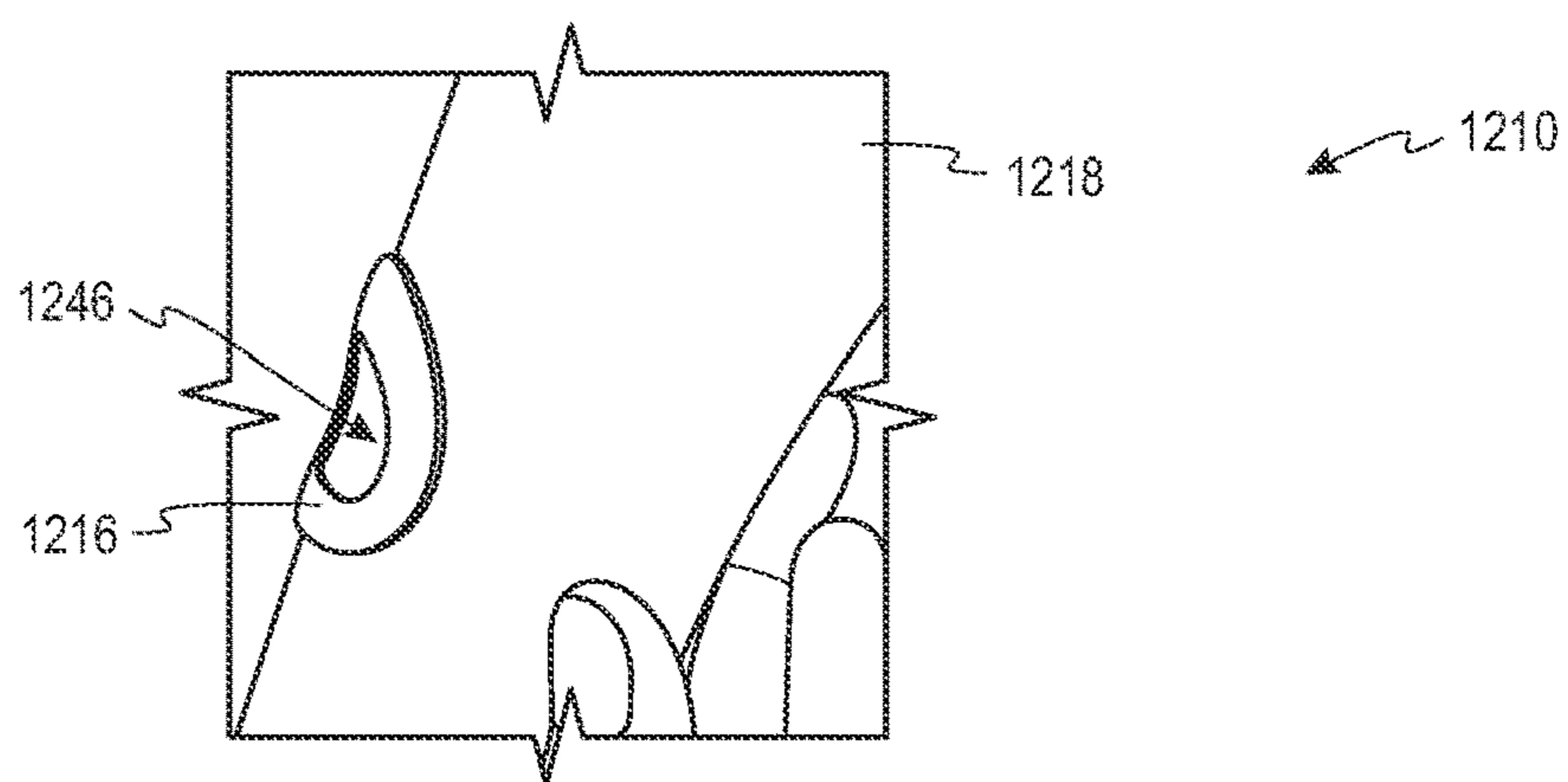


Fig. 12C

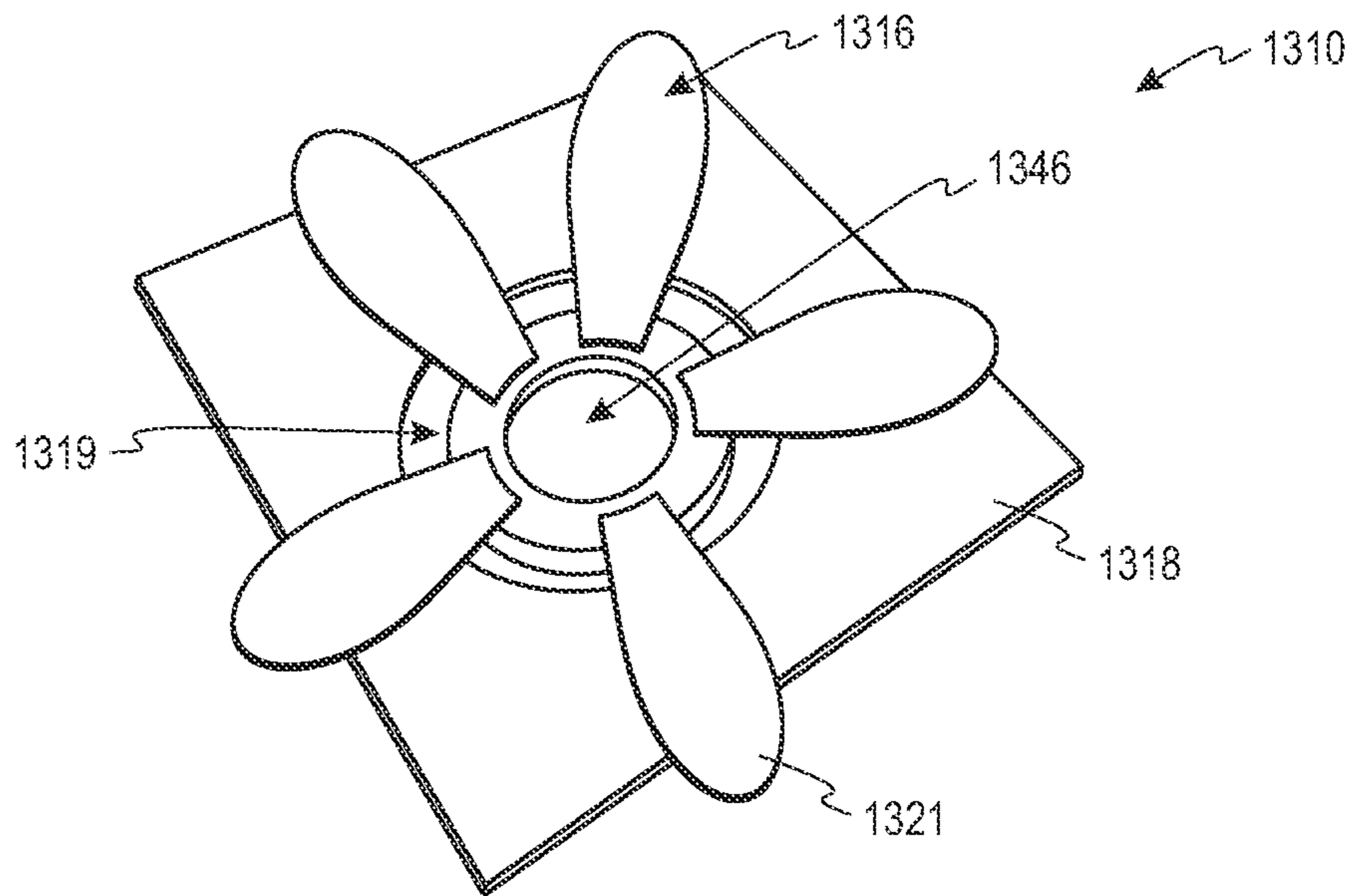


Fig. 13A

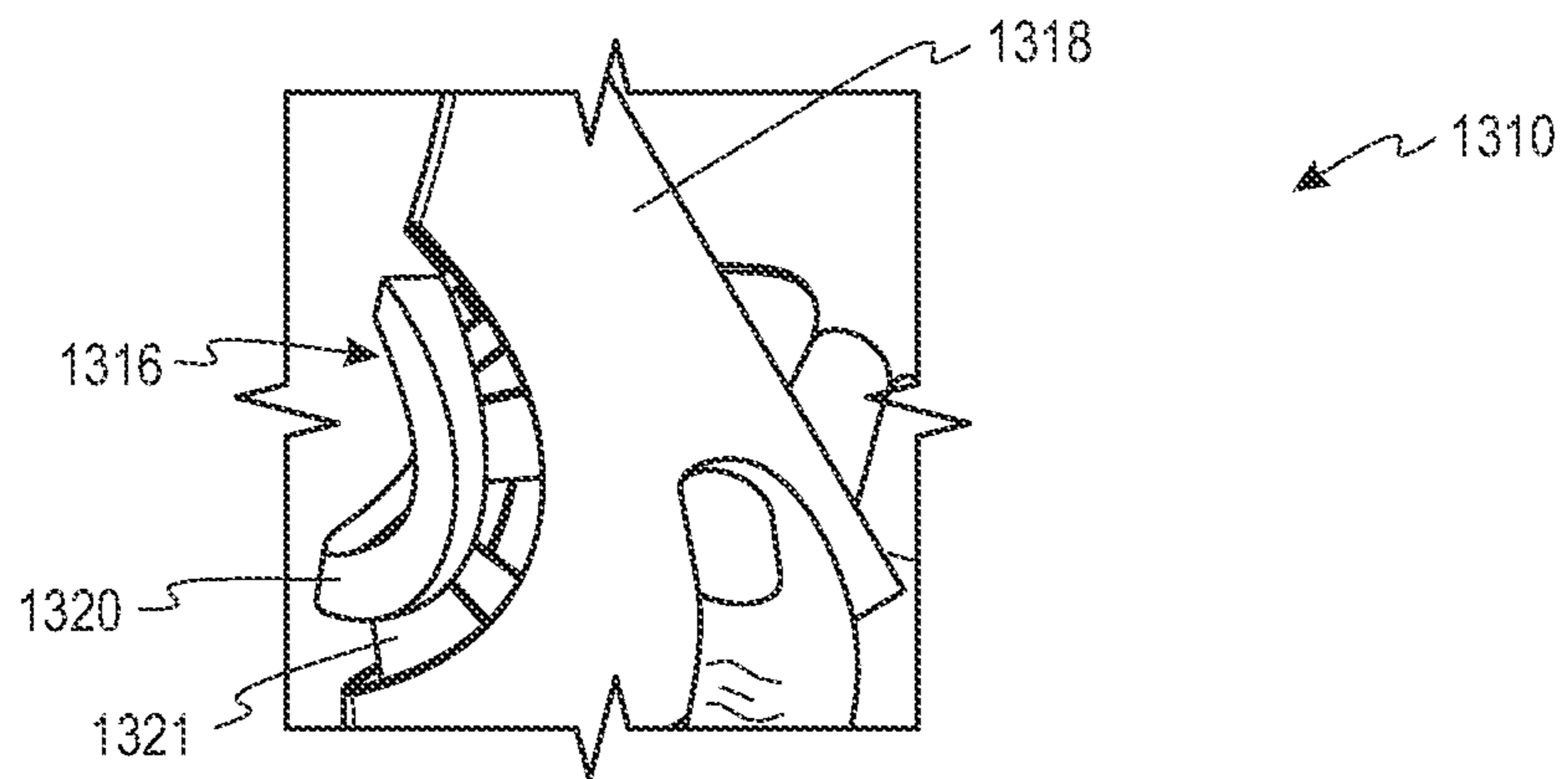


Fig. 13B

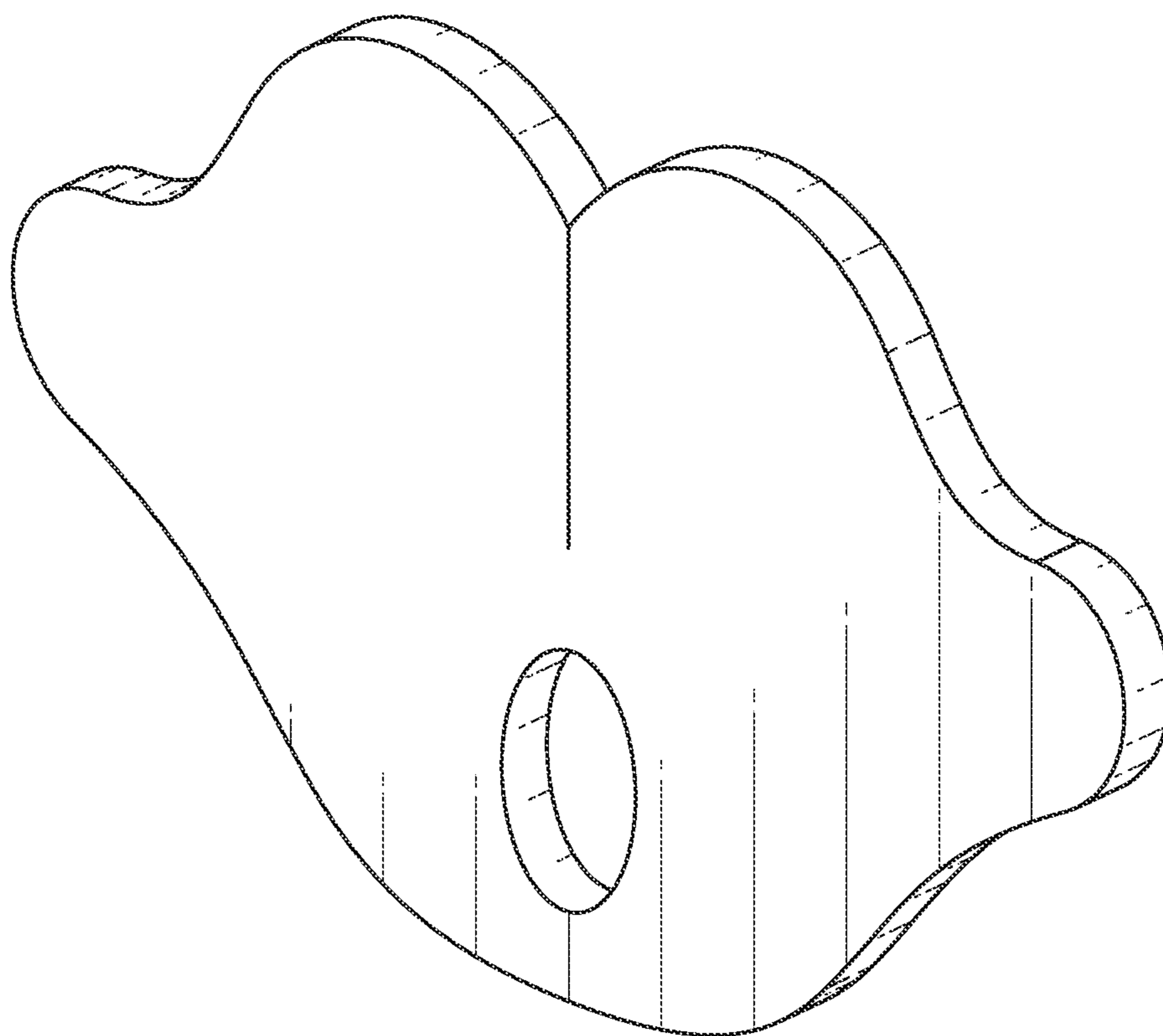


Fig. 14

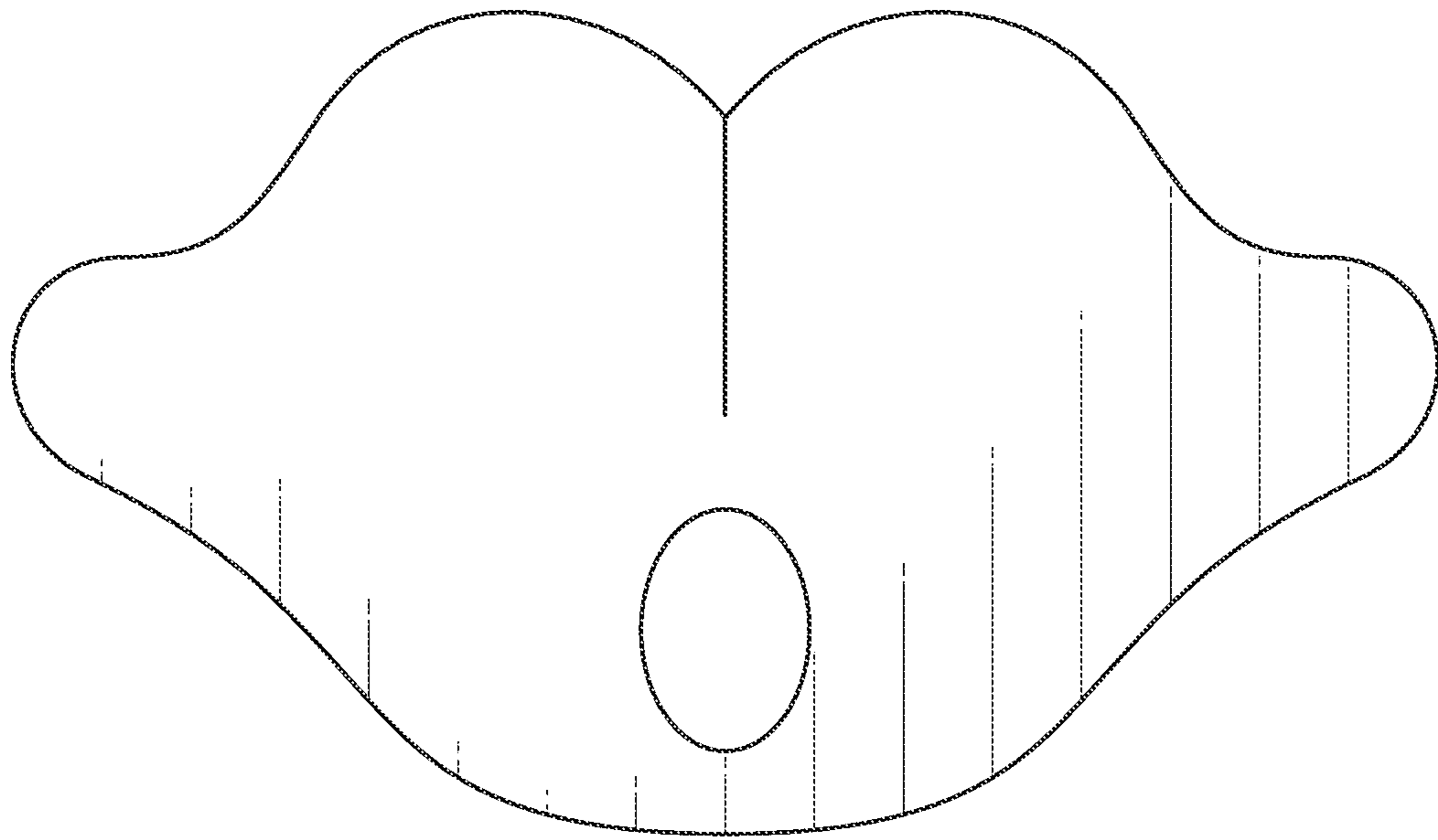


Fig. 15

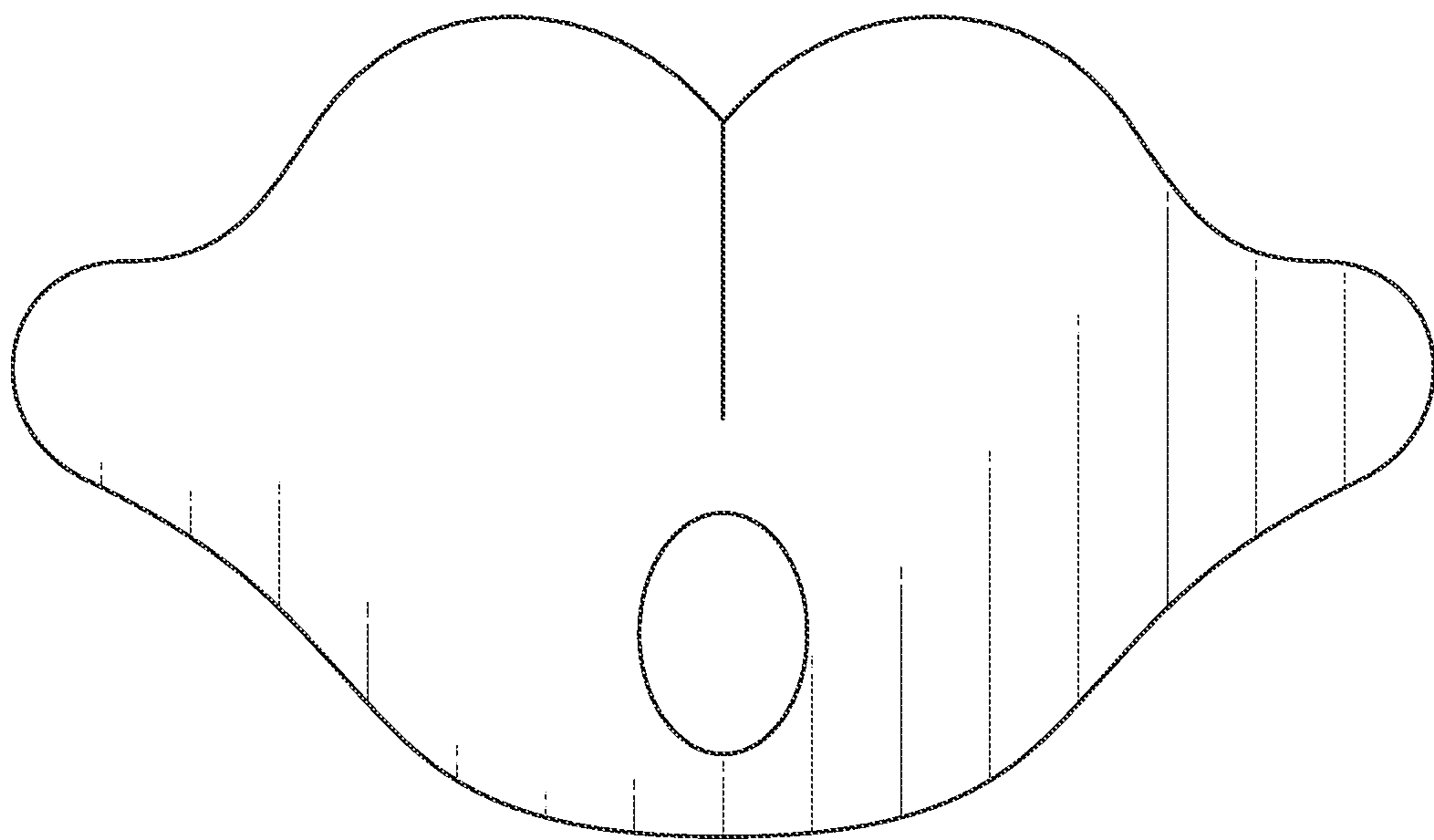


Fig. 16



Fig. 17

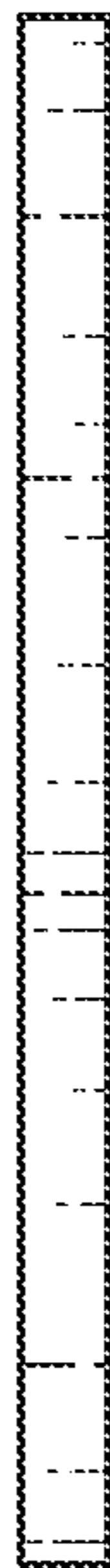


Fig. 18

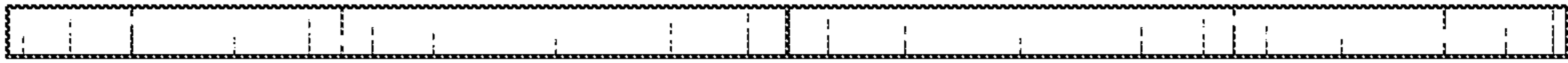


Fig. 19



Fig. 20

1**FECAL COLLECTION SYSTEMS AND METHODS****CROSS-REFERENCE TO RELATED APPLICATION**

The present application claims the benefit of U.S. Provisional Application No. 63/014,684, filed Apr. 23, 2020, the contents of which is hereby incorporated by reference in its entirety.

FIELD

The present disclosure generally relates to fecal collection devices and systems for collecting feces discharged from the body of a user and carrying the feces away from the body.

BACKGROUND

Under various circumstances, a user may have limited or impaired mobility such that ordinary bowel movement functions and processes are rendered difficult (or impossible). For example, a person may have impaired mobility due to a disability or may be bedridden due to an injury or illness. Also, for example, feces collection may be needed for monitoring purposes, such as for monitoring inputs and outputs in a clinical setting (e.g., in an intensive care unit, or for other clinical and/or laboratory testing).

Various approaches have been developed to address some of the problems or circumstances related to impaired or restricted bowel movement processes. However, prior approaches suffer from problems or limitations of their own.

SUMMARY

In an example, a fecal collection system is described. The fecal collection system includes a user interface assembly, a drainage conduit, and a collection reservoir. The user interface assembly includes a user interface and an applicator. The user interface has a proximal side and a distal side. The proximal side is configured to couple to skin of a user. The applicator is coupled to the distal side of the user interface. The applicator is removable from the user interface while the user interface is coupled to the user. The drainage conduit extends between a proximal end and a distal end. The proximal end is configured to couple to the distal side of the user interface. The drainage conduit defines a lumen configured to guide feces from the proximal end to the distal end. The collection reservoir is coupled to the distal end of the drainage conduit.

In another example, a method of using a fecal collection system is described. The method includes positioning a user interface assembly at an anus of a user. The user interface assembly includes a user interface and an applicator. The method also includes coupling the user interface to the skin of the user by using the applicator to press the user interface against the skin of the user. The method further includes, after coupling the user interface to the skin of the user, removing the applicator from the user interface.

The features, functions, and advantages that have been discussed can be achieved independently in various embodiments or may be combined in yet other embodiments further details of which can be seen with reference to the following description and drawings.

BRIEF DESCRIPTION OF THE FIGURES

The novel features believed characteristic of the illustrative embodiments are set forth in the appended claims. The

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illustrative embodiments, however, as well as a preferred mode of use, further objectives and descriptions thereof, will best be understood by reference to the following detailed description of an illustrative embodiment of the present disclosure when read in conjunction with the accompanying drawings, wherein:

FIG. 1 illustrates a simplified block diagram of a fecal collection system, according to an example.

FIG. 2 illustrates an implementation of the fecal collection system shown in FIG. 1, according to an example.

FIGS. 3A-3D illustrate a process for coupling a user interface assembly to the skin of a user according to one example implementation of the user interface assembly shown in FIG. 1.

FIG. 4 illustrates a proximal side of the user interface according to an example.

FIG. 5 illustrates a drainage conduit and a collection reservoir according to an example.

FIG. 6 illustrates an implementation of the fecal collection system shown in FIG. 1, according to another example.

FIG. 7 illustrates a distal side of an applicator for the fecal collection system shown in FIG. 6, according to an example.

FIG. 8A illustrates the user interface in a folded state for the fecal collection system shown in FIG. 6, according to an example.

FIG. 8B illustrates the user interface for the fecal collection system shown in FIG. 6, according to an example.

FIGS. 9A-9J illustrate a process for coupling the fecal collection system of FIG. 6 to a user, according to an example.

FIG. 10A illustrates a distal side of a user interface, according to an example.

FIG. 10B illustrates a proximal side of the user interface shown in FIG. 10A, according to an example.

FIG. 11A depicts a user interface, according to another example.

FIG. 11B depicts the user interface of FIG. 11A coupled to a user, according to an example.

FIG. 12A depicts a user interface assembly in a first configuration, according to another example.

FIG. 12B depicts the user interface assembly of FIG. 12A in a second configuration, according to an example.

FIG. 12C depicts the user interface assembly of FIG. 12A in the first configuration while the user interface assembly is being applied to a user, according to an example.

FIG. 13A depicts a user interface assembly in a first configuration, according to another example.

FIG. 13B depicts the user interface assembly of FIG. 13A in the first configuration while the user interface assembly is being applied to a user, according to an example.

FIG. 14 is a perspective view of an applicator, according to an example.

FIG. 15 is a first side view of the applicator shown in FIG. 14, according to the example.

FIG. 16 is a second side view of the applicator shown in FIG. 14, according to the example.

FIG. 17 is a first side view of the applicator shown in FIG. 14, according to the example.

FIG. 18 is a second side view of the applicator shown in FIG. 14, according to the example.

FIG. 19 is a first side view of the applicator shown in FIG. 14, according to the example.

FIG. 20 is a second side view of the applicator shown in FIG. 14, according to the example.

DETAILED DESCRIPTION

Disclosed embodiments will now be described more fully hereinafter with reference to the accompanying drawings, in

which some, but not all of the disclosed embodiments are shown. Indeed, several different embodiments may be described and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are described so that this disclosure will be thorough and complete and will fully convey the scope of the disclosure to those skilled in the art.

Referring to FIG. 1, a simplified block diagram of a fecal collection system **100** is shown according to an example. As shown in FIG. 1, the fecal collection system **100** includes a user interface assembly **110**, a drainage conduit **112**, and a collection reservoir **114**. The fecal collection system **100** can be coupled to the skin of the user such that the fecal collection system **100** is external to the body of the user.

The user interface assembly **110** includes a user interface **116** and an applicator **118**. The user interface **116** has a proximal side and a distal side. The proximal side is configured to couple to the skin of a user. For instance, the user interface **116** can include an adhesive sheet **120** on the proximal side. As one example, the adhesive sheet **120** can include a biocompatible adhesive such as, for instance, a silicon adhesive that can provide for coupling the user interface **116** to the skin of the user. In one example, the adhesive sheet **120** can be configured to couple the user interface **116** to the user's skin for a period of at least eight hours before being removed and/or replaced. In another example, the adhesive sheet **120** can be configured to couple the user interface **116** to the user's skin for a period of approximately 12 to 72 hours before being removed and/or replaced.

The applicator **118** is coupled to the distal side of the user interface **116**. The applicator **118** is removable from the user interface **116** while the user interface **116** is coupled to the user. In this arrangement, the applicator **118** can assist in coupling the user interface **116** to the skin of the user, and then be removed to provide for coupling the drainage conduit **112** to the user interface **116** and/or reduce an amount of material of the fecal collection system **100** between the user and a support structure (e.g., a hospital bed and/or wheel chair). Removing the applicator **118** can thus help to mitigate a risk of pressure sores.

The drainage conduit **112** extends between a proximal end and a distal end. In one example, the proximal end of the drainage conduit **112** can be fixedly coupled to the distal side of the user interface **116** before the applicator **118** is removed from the user interface **116**. In this example, the drainage conduit **112** can be coupled to the user interface **116** while the user interface **116** is being coupled to the skin of the user. In another example, the proximal end is configured to couple to the distal side of the user interface **116** after the applicator **118** is removed from the user interface **116**. More generally, the drainage conduit **112** defines a lumen configured to guide feces from the proximal end to the distal end. The collection reservoir **114** coupled to the distal end of the drainage conduit **112**. The collection reservoir **114** is configured to contain the feces.

The drainage conduit **112** and the lumen can have an elongated shape. In an example, the drainage conduit **112** can have a length of approximately 4 feet to approximately 6 feet. This length can help to position the collection reservoir **114** at a location that is remote from the user (e.g., at a side of a patient support structure such as a hospital bed). However, the drainage conduit **112** can have a different length in other examples.

Additionally, in some examples, the drainage conduit **112** can be configured to guide the feces from the proximal end to the distal end responsive to milking the drainage conduit

112 toward the collection reservoir **114** (e.g., by applying compression to the drainage conduit **112** along a length of drainage conduit **112** in a direction from the proximal end to the distal end). For instance, the drainage conduit **112** can have a hardness and/or a pliability that facilitates manually milking the feces toward the collection reservoir **114**. Also, as examples, the drainage conduit **112** can be formed from a polyurethane (PU) and/or a polyvinyl chloride (PVC). For instance, the drainage conduit **112** can be a film tube having a thickness between approximately 2 mil and approximately 4 mil.

In some implementations, the drainage conduit **112** can be at least partially transparent or translucent. This can help to determine whether feces is present in the drainage conduit **112** such that a determination can be made to milk the drainage conduit **112** and force the feces to the collection reservoir **114**.

In an alternative example, the fecal collection system **100** can omit the drainage conduit **112** such that the collection reservoir **114** is directly coupled to the user interface **116**. Although this may reduce a cost of manufacture and reduce a need to milk the drainage conduit **112**, the collection reservoir **114** is positioned nearer to the user, which increases a bulk of the device that may contact the user and makes replacing the collection reservoir **114** more challenging.

As noted above, the user interface **116** can include the adhesive sheet **120**. The adhesive sheet **120** can define an aperture in communication with the lumen of drainage conduit **112**. In this arrangement, feces can pass from an anus of the user into the drainage conduit **112** through the aperture of the adhesive sheet **120**. The drainage conduit **112** can then guide the feces to the collection reservoir **114**.

In one example, the aperture of the adhesive sheet **120** can have a diameter of approximately 1.5 inches. This can help to provide a sufficiently large opening to receive the feces into the drainage conduit **112** while allowing for a surface area of the adhesive sheet **120** to secure the fecal collection system **100** to the skin of the user. In another example, the aperture of the adhesive sheet **120** can have a diameter of approximately 1 inch to approximately 2 inches.

In some implementations, the user interface **116** can also include a collar **122** extending distally from the adhesive sheet **120**. As described above, the adhesive sheet **120** can include an adhesive such as, for example, a silicon adhesive that can provide for coupling the user interface **116** to the skin of the user. The proximal end of the drainage conduit **112** can be coupled to the collar **122** of the user interface **116**. For example, the collar **122** can be a foam wedge and can be received at the proximal end of the drainage conduit **112**. In this example, the collar **122** can thus couple to the drainage conduit **112** by friction-fit connection. However, in other examples, the collar **122** can additionally or alternatively couple to the drainage conduit **112** by a threaded connection, a hook and loop connection, and/or an adhesive connection.

More generally, the collar **122** can be configured to provide for coupling, decoupling, and/or recoupling one or more drainage conduits **112** to the user interface **116**. As such, the collar **122** can provide for changing the drainage conduit **112** and/or the collection reservoir **114** without removing the user interface from **116** from the user. For instance, a method of using the fecal collection system **100** can include removing a first drainage conduit **112** from the user interface **116** after an initial period of use (e.g., approximately 8 hours) and then coupling a second drainage conduit **112** to the user interface **116**.

In an example, the collar **122** can define a first aperture in communication with the lumen of drainage conduit **112**, and the adhesive sheet **120** can define a second aperture that is axially aligned with the first aperture of the collar **122**. In this arrangement, feces can pass from an anus of the user into the drainage conduit **112** through the first aperture of the collar **122** and the second aperture of the adhesive sheet **120**. The drainage conduit **112** can then guide the feces to the collection reservoir **114**.

In one example, the first aperture and the second aperture can have a diameter of approximately 1.5 inches. This can help to provide a sufficiently large opening to receive the feces into the drainage conduit **112** while allowing for a surface area of the adhesive sheet **120** to secure the fecal collection system **100** to the skin of the user. In another example, the first aperture and/or the second aperture can have a diameter of approximately 1 inches to approximately 2 inches.

In an example, the fecal collection system **100** can also include a first one-way valve **124** in the lumen defined by the drainage conduit **112**. The first one-way valve **124** is configured to allow feces to flow in a direction from the proximal end to the distal end of the drainage conduit **112** and inhibit the feces from flowing in a direction from the distal end to the proximal end of the drainage conduit **112**. This can help inhibit feces from migrating back toward and into contact with the skin of the user.

In one example, the first one-way valve **124** can be configured to transition from a closed state to an open state responsive to feces passing through the first one-way valve **124** in a distal direction (e.g., from the user toward the drainage conduit **112**). In the closed state, the first one-way valve **124** can inhibit backflow of feces in a proximal direction toward the user (e.g., toward the user interface assembly **110**). In the open state, the first one-way valve **124** can expand to define an enlarged passageway that allows the feces to pass through the first one-way valve **124** in a distal direction. In one implementation, the first one-way valve **124** can be configured to expand to have a diameter that is approximately equal to a diameter of the drainage conduit **112**. For instance, in an implementation in which the drainage conduit **112** has a diameter of approximately 1.5 inches, the first one-way valve **124** can expand from a diameter of approximately zero inches in the closed state to a diameter of approximately 1.5 inches in the open state.

In one example implementation, the first one-way valve **124** can include a plurality of flaps that extend distally from a proximal end of the drainage conduit **112** (e.g., at the aperture of the adhesive sheet **120**). In this arrangement, the flaps can taper towards each other along a length of the flaps in a direction from the proximal end of the drainage conduit **112** toward a distal end of the drainage conduit **112**. In one example, a material of the flaps can be the same as a material of the drainage conduit **112**. The flaps can be a monolithic structure (e.g., integral) with the drainage conduit **112** or the flaps can be distinct structures coupled to the drainage conduit **112** (e.g., via a weld).

The collection reservoir **114** can additionally or alternatively include a second one-way valve **126** that is configured to allow feces to flow from the drainage conduit **112** to the collection reservoir **114** and inhibit the feces from flowing from the collection reservoir **114** to the drainage conduit **112**. This can also help inhibit feces from migrating back toward and into contact with the skin of the user. In one example, the drainage conduit **112** can have a diameter of approximately 1 inch to approximately 3 inches at the distal end **212B**.

FIG. 2 depicts an implementation of the fecal collection system **100** according to an example. As shown in FIG. 2, the fecal collection system **100** includes the user interface assembly **110**, the drainage conduit **112**, and the collection reservoir **114** as described above. As described above, the user interface assembly **110** includes the user interface **116** having a proximal side **216A** and a distal side **216B**. Additionally, in FIG. 2, the drainage conduit **112** extends between a proximal end **212A** and a distal end **212B**.

As shown in FIG. 2, the drainage conduit **112** can be configured to be coupled, decoupled, and re-coupled to the collection reservoir **114**. This can provide for decoupling a first collection reservoir **114** containing feces, and coupling a second collection reservoir **114** that is empty to continue collecting feces without having to decouple the user interface **116** and/or the drainage conduit **112** from the skin of the user. In some examples, the drainage conduit **112** and the collection reservoir **114** can be coupled, decoupled, and recoupled to the user interface **116** while the user interface **116** remains coupled to the skin of the user. This can provide for changing the drainage conduit **112** and/or the collection reservoir **114** without removing the user interface from **116** from the user. In other examples, the drainage conduit **112** can be permanently fixed to the collection reservoir **114**. This can help to mitigate a risk of leakage at an interface between the user interface **116** and the drainage conduit **112**.

Additionally, as shown in FIG. 2, the collection reservoir **114** can include a measurement window **230** including a plurality of volumetric markings **232**. The measurement window **230** can be at least one of transparent or translucent such that a quantity of feces in the collection reservoir **114** can be visually observed. This can provide an indication when the collection reservoir **114** should be changed, and/or when sufficient volume of feces has been collected to provide a sample for a diagnostic evaluation.

In FIG. 2, the first one-way valve **124** is positioned at the proximal end **214A**. In other examples, the first one-way valve **124** can be positioned between the proximal end **214A** and the distal end **214B** of the drainage conduit **112**.

FIGS. 3A-3D depict a process for coupling the user interface assembly **110** to the skin of a user according to one example implementation of the user interface assembly **110**. As shown in FIGS. 3A-3D, the user interface assembly **110** includes the user interface **116** and the applicator **118**. In FIG. 3A, the user interface assembly **110** is positioned at an anus **340** of the user. The user interface assembly **110** is folded such that the proximal side **216A** of the user interface **116** faces outward, and the distal side **216B** of the user interface **116** faces inward.

In FIG. 3B, the applicator **118** is used to press the proximal side **216A** of the user interface **116** against the skin **342** of the user. In this example, the applicator **118** includes a first lateral portion **318A** and a second lateral portion **318B** that are hingedly movable relative to each other. For instance, the applicator **118** can include a hinged portion **318D** between the first lateral portion **318A** and the second lateral portion **318B**. In this example, the hinged portion **318C** is perforated to assist in removing the applicator **118** from the user interface **116**. As shown in FIG. 3B, the first lateral portion **318A** of the applicator **118** and a second lateral portion **318B** of the applicator **118** can be moved relative to each other to press the user interface **116** against the skin **342** of the user.

In FIG. 3C, the applicator **118** is being removed from the user interface **116**. For example, the applicator **118** can be removed from the user interface **116** by decoupling the first lateral portion **318A** and the second lateral portion **318B**

from the user interface **116** along the perforation line of the hinged portion **318C**. As shown in FIGS. **3C-3D**, the removing the applicator **118** can expose the collar **122** of the user interface **116**. In FIG. **3D**, the user interface **116** is coupled to the skin **342** of the user. As shown in FIG. **3D**, the adhesive sheet **120** is coupled to the skin **342** and the collar **122** extends distally from the adhesive sheet **120**. Also, in FIG. **3D**, the collar **122** defines a first aperture **344**, the adhesive sheet **120** defines a second aperture **346**, and the first aperture **344** and the second aperture **346** are aligned with the anus **340** of the user.

FIG. **4** depicts the proximal side **216A** of the user interface **116** according to an example. In FIG. **4**, the user interface **116** includes a release liner **448** that covers and adhesive on the proximal side **216A** of the user interface **116**. The release liner **448** can be removed to expose the adhesive prior to coupling the user interface **116** to the skin of the user.

FIG. **5** depicts the drainage conduit **112** and the collection reservoir **114** according to an example implementation.

Referring now to FIG. **6**, a fecal collection system **600** is depicted for an implementation of the fecal collection system **100** according to another example. As shown in FIG. **6**, the fecal collection system **600** includes the user interface assembly **110**, the drainage conduit **112**, and the collection reservoir **114** as described above. As described above, the user interface assembly **110** includes the user interface **116** having a proximal side and a distal side. Additionally, in FIG. **6**, the drainage conduit **112** extends between a proximal end **612A** and a distal end **612B**.

As shown in FIG. **6**, the drainage conduit **112** can be configured to be coupled, decoupled, and re-coupled to the collection reservoir **114**. This can provide for decoupling a first collection reservoir **114** containing feces, and coupling a second collection reservoir **114** that is empty to continue collecting feces without having to decouple the user interface **116** from the skin of the user. In other examples, the drainage conduit **112** can be permanently fixed to the collection reservoir **114**. In such examples, the drainage conduit **112** and the collection reservoir **114** can be coupled, decoupled, and recoupled to the user interface **116** while the user interface **116** remains coupled to the skin of the user (e.g., in other examples, the user interface **110** can further include the collar **122** described above).

In FIG. **6**, the distal end **612B** of the drainage conduit **112** includes a male quick-connect coupler **650A** that can couple to a female quick-connect coupler **650B** of the collection reservoir **114**. The female quick-connect coupler **650B** of the collection reservoir **114** further includes an actuator **650C** (e.g., a button) that is operable to couple and/or decouple the male quick-connect coupler **650A** and the female quick-connect coupler **650B** to each other. In this arrangement, the drainage conduit **112** can remain securely coupled to the collection reservoir **114** until the actuator **650C** is operated to decouple the male quick-connect coupler **650A** of the drainage conduit **112** from the female quick-connect coupler **650B** of the collection reservoir **114**. This can help to inhibit (or prevent) inadvertent decoupling of the drainage conduit **112** and the collection reservoir **114**. Although the drainage conduit **112** includes the male quick-connect coupler **650A** and the collection reservoir **114** includes the female quick-connect coupler **650B** in FIG. **6**, the drainage conduit **112** can include the female quick-connect coupler **650B** and the collection reservoir **114** can include the male quick-connect coupler **650A** in an alternative example.

Additionally, as described above, the collection reservoir **114** can include a measurement window including a plurality

of volumetric markings (e.g., similar to the collection reservoir **114** shown in FIGS. **2** and **5**). The measurement window can be at least one of transparent or translucent such that a quantity of feces in the collection reservoir can be visually observed. This can provide an indication when the collection reservoir should be changed, and/or when sufficient volume of feces has been collected to provide a sample for a diagnostic evaluation.

In FIG. **6**, the proximal end **612A** of the drainage conduit **112** is coupled to the distal side of the user interface **116**. In this example, the drainage conduit **112** can be non-removably coupled (e.g., fixedly and permanently coupled) to the user interface **116**. For instance, the proximal end **612A** of the drainage conduit **112** can be welded to the adhesive sheet **120** at an aperture **646** in the adhesive sheet **120**.

FIG. **7** depicts the applicator **118** according to the example shown in FIG. **6**. As shown in FIG. **7**, the applicator **118** includes a first lateral portion **718A**, a second lateral portion **718B**, and a hinge portion **718C** between the first lateral portion **718A** and the second lateral portion **718B**. In this arrangement, the first lateral portion **718A** and the second lateral portion **718B** are configured to move about the hinge portion **718C** between an extended state (as shown in FIG. **7**) and a folded state (as shown in FIGS. **8A-8B**). As described below, the folded state can help to insert the applicator **118** and the user interface **116** between buttocks to access an anus of a user. The extended state can help remove the applicator **118** from the user interface **116**, as described above.

The hinge portion **718C** is further configured to facilitate removing the applicator **118** from the user interface **116**. For example, in FIG. **7**, the hinge portion **718C** includes a first bridge portion **752A** and a second bridge portion **752B** connecting the first lateral portion **718A** of the applicator **118** to the second lateral portion **718B** of the applicator **118** (e.g., the first lateral portion **718A** and the second lateral portion **718B** can be coupled to each other only at the first bridge portion **752A** and the second bridge portion **752B**). The first bridge portion **752A** and the second bridge portion **752B** can have a size that is relatively small compared to an overall size of the applicator **718** in a dimension extending along an intersection between the first lateral portion **718A** and the second lateral portion **718B**. For instance, a combined length of the first bridge portion **752A** and the second bridge portion **752B** can be less than approximately 50 percent of an overall length of the applicator **118** in this dimension. This relative size can provide for (i) inhibiting inadvertent separation of the first lateral portion **718A** and the second lateral portion **718B** during coupling of the user interface **116** to the user and (ii) easily tearing the first lateral portion **718A** and the second lateral portion **718B** apart from each other after coupling the user interface **116** to the user.

In some implementations, the first bridge portion **752A** and/or the second bridge portion **752B** can include perforations to assist in decoupling the first lateral portion **718A** and the second lateral portion **718B** from each other. The perforations can allow for the combined length of the first bridge portion **752A** and the second bridge portion **752B** to be greater than approximately 50 percent of an overall length of the applicator **118** in the dimension extending along an intersection between the first lateral portion **718A** and the second lateral portion **718B** (e.g., along the hinge portion **718C**).

Additionally, as shown in FIG. **7**, the drainage conduit **112** extends through an aperture **754** in the applicator **118**. The first bridge portion **752A** is defined between the aperture **754** and a slit **756**, which extends along the hinge portion **718C**

between the first lateral portion **718A** and the second lateral portion **718B** of the applicator **718**. The slit **756** can help to reduce a size of the first bridge portion **752A** relative to the overall size of the applicator **718** along the interface between the first lateral portion **718A** and the second lateral portion **718B**. The slit **756** can additionally or alternatively help to enhance the movability of the first lateral portion **718A** and the second lateral portion **718B** about the hinge portion **752C**.

In one example, the slit **756** can have a length that is greater than approximately 40 percent of the overall length of the applicator **118** in the dimension extending along the hinge portion **718C** (e.g., a dimension through the first bridge portion **752A**, the aperture **754**, and the second bridge portion **752B**). This can help to achieve the functionalities of the slit **756** described above.

The second bridge portion **752B** can be defined between the aperture **754** (e.g., at a point that is opposite the first bridge portion **752A**) and a peripheral edge of the applicator **118** at the hinge portion **718C**. As shown in FIG. 7, the aperture **754** can be at a location that is offset from a center of the applicator **118**. More particularly, the aperture **754** can be at position that is closer to a lower edge of the applicator **118** than an upper edge of the applicator **118**. As such, the proximal end of the drainage conduit **112** can be coupled to the user interface **116** at a location that is offset below a center of the user interface **116**. This can help to apply the user interface **116** at the anus of the user, which is generally located at a position that is below a center of the user's buttocks.

As shown in FIG. 7, the applicator **118** can further include a first tab **758A** on a peripheral edge of the first lateral portion **718A** and a second tab **758B** on a peripheral edge of the second lateral portion **718B**. The first tab **758A** and the second tab **758B** can extend laterally past a peripheral edge of the user interface **116** such that the first tab **758A** and the second tab **758B** can facilitate gripping and handling of the applicator **118** when positioning the user interface assembly **110** between a user's buttocks.

FIGS. 8A-8B depict the user interface **116** and the applicator **118** in the folded state such that the first lateral portion **718A** and the second lateral portion **718B** are folded about the hinge portion **718C**, and the user interface **116** is positioned externally to the applicator **118**. As shown in FIG. 8A, the applicator **118** can have a size that is larger than the user interface **116** (e.g., the first tab **758A** and the second tab **758B** can extend past a peripheral edge of the user interface **116**). This can help provide access to the applicator **118**. In another example, the applicator can have a size that is approximately equal to a size of the user interface **116**. More generally, the user interface **116** and the applicator **118** can be configured to provide for holding the user interface **116** and the applicator **118** in a single hand while the user interface **116** and the applicator **118** are in a folded state.

In FIGS. 8A-8B, the user interface **116** includes the adhesive sheet **120** (shown in FIG. 8B), a first release liner **860**, and a second release liner (not shown in FIGS. 8A-8B). The first release liner **860** is removably coupled to a first half of the adhesive sheet **120** (e.g., on a first side of the hinge portion **718C** and the aperture **754** in FIGS. 8A-8B), and the second release liner is removably coupled to a second half of the adhesive sheet **120** (e.g., on a second side of the hinge portion **718C** and the aperture **754** in FIGS. 8A-8B). In this arrangement, the first release liner **860** and the second release liner can be independently removed from the adhesive sheet **120** to provide for coupling the user interface **116** to the user's skin on one side at a time.

The first release liner **860** can include a first portion **860A** and a second portion **860B**. The first portion **860A** can cover the first half of the adhesive sheet **120** to inhibit the adhesive sheet **120** prematurely or inadvertently adhering to an object prior to application of the user interface **116** to the user. The second portion **860B** can have a first end that is coupled to the first portion **860A** at an inner portion of the user interface **116** (e.g., at the aperture **754**), and a second end that is separate from the first portion **860A** at an outer portion of the user interface **116** (e.g., at the peripheral edge of the user interface **116**). In this arrangement, a practitioner can grasp the second end at the periphery of the user interface **116** and pull outwardly away from the user to separate the first portion **860A** of the first release liner **860** from the adhesive sheet **120**. In this way, the first release liner **860** can be progressively expose the first half the adhesive sheet **120** in a direction from the aperture **754** towards the peripheral edge of the user interface **116**. This can help to improve coupling the adhesive sheet **120** to the buttocks of the user with the aperture **754** aligned with the anus of the user.

Although not shown in FIGS. 8A-8B, the second release liner can be arranged in a similar manner with respect to the second half of the adhesive sheet **120**. As such, the second release liner can include a first portion and a second portion. The first portion of the second release liner can cover the second half of the adhesive sheet **120** to inhibit the adhesive sheet **120** prematurely or inadvertently adhering to an object prior to application of the user interface **116** to the user. The second portion can have a first end that is coupled to the first portion at an inner portion of the user interface **116** (e.g., at the aperture **754**), and a second end that is separate from the first portion at an outer portion of the user interface **116** (e.g., at the peripheral edge of the user interface **116**). In this arrangement, a practitioner can grasp the second end at the periphery of the user interface **116** and pull outwardly away from the user to separate the first portion of the second release liner from the adhesive sheet **120**. In this way, the second release liner can be progressively expose the second half the adhesive sheet **120** in a direction from the aperture **754** towards the peripheral edge of the user interface **116**. This can help to improve the coupling the adhesive sheet **120** to the buttocks of the user with the aperture **754** aligned with the anus of the user.

As shown in FIG. 8B, the first half and the second half of the adhesive sheet **120** can each include a grip region **864**. The grip region **864** can be located at the outer periphery of the adhesive sheet **120** and omit the adhesive. This can allow a practitioner to hold the grip region **864** to manipulate and handle the adhesive sheet **120** while applying the adhesive sheet **120** to the user's buttocks. The grip region **864** can also facilitate easier removal of the adhesive sheet **120** from the user as compared to an alternative implementation in which the adhesive extends over an entire surface area of the adhesive sheet **120**.

Additionally, as shown in FIG. 8B, the user interface **116** and/or the applicator **118** can include an alignment indicator **866** that can help to align the aperture **754** and the drainage conduit **112** with the anus of the user. For example, in FIG. 8B, the alignment indicator **866** includes a first line that extends on the applicator **118** from a top of the aperture **754** to the peripheral edge of the adhesive sheet **120**, and a second line that extends on the applicator **118** from a bottom of the aperture **754** to the peripheral edge of the adhesive sheet **120**. In this arrangement, the alignment indicator **866** can provide a visual indication of the location of the aperture **754** of the applicator **118**, the aperture **646** of the user interface **116** (shown in FIG. 6), and the drainage conduit

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112 positioned between the buttocks even though the aperture 754 and the aperture 646 cannot be directly visualized.

Referring now to FIGS. 9A-9J, process for coupling the fecal collection system 600 to a user is depicted according to one example implementation of the user interface assembly 110. In FIG. 9A, the user interface assembly 110 is inserted between the buttocks of the user. For instance, with the applicator 118 in the folded state, a medical practitioner can hold the first tab 758A and the second tab 758B of the applicator 118 along with the grip regions 864 of the adhesive sheet 120. As shown in FIG. 9A, this allows the medical practitioner to hold the user interface assembly 110 at a location remote from the buttocks while positioning the aperture in the user interface 116 and the drainage conduit 112 at the anus.

In FIG. 9B, the first release liner 860 is removed from the first half of the adhesive sheet 120. For example, the medical practitioner can grasp the second end at the periphery of the user interface 116 and pull outwardly away from the user to separate the first portion 860A of the first release liner 860 from the adhesive sheet 120. In this way, the first release liner 860 can be progressively expose the first half the adhesive sheet 120 in a direction from the aperture 754 towards the peripheral edge of the user interface 116.

In FIG. 9C, after the first release liner 860 is removed from the adhesive sheet 120, the medical practitioner can use the alignment indicator 866 to determine the position of the aperture relative to the anus of the user. In some instance, the medical practitioner can use the applicator 118 to adjust a position of the user interface 116 relative to the user based on a position of the alignment indicator relative to the anus of the user.

In FIG. 9D, the first half 920A of the adhesive sheet 120 can be coupled to the skin of the user on a first buttock. Additionally, as shown in FIG. 9D, the medical practitioner can use one hand to hold the applicator 118 in position at the anus while using the other hand to place the first half 920A of the adhesive sheet 120 on the first buttock (e.g., by holding the grip region 864 of the adhesive sheet 120).

In FIG. 9E, the second release liner 960 is removed from the second half of the adhesive sheet 120. For example, the medical practitioner can grasp the second end at the periphery of the user interface 116 and pull outwardly away from the user to separate the first portion 960A of the second release liner 960 from the adhesive sheet 120. In this way, the second release liner 960 can be progressively expose the second half the adhesive sheet 120 in a direction from the aperture 754 towards the peripheral edge of the user interface 116.

In FIG. 9F, the second half 920B of the adhesive sheet 120 can be coupled to the skin of the user on a second buttock. Additionally, as shown in FIG. 9F, the medical practitioner can use one hand to hold the applicator 118 in position at the anus while using the other hand to place the second half 920B of the adhesive sheet 120 on the second buttock (e.g., by holding the grip region 864 of the adhesive sheet 120).

FIG. 9G depicts the applicator 118 being removed from the user interface 116 and FIG. 9H depicts the user interface 116 and the drainage conduit 112 after the applicator 118 has been removed from the user interface 116. For example, as shown in FIG. 9G, the first lateral portion 718A and the second lateral portion 718B can be torn apart from each other (e.g., at the first bridge portion 752A and/or the second bridge portion 752B). This can facilitate completely removing the applicator 118, which can help to improve user comfort and reduce pressure on the user's buttocks. However, in another example, the applicator 118 can be

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decoupled from the remainder of the user interface 116 (e.g., the adhesive sheet 120 and the collar 122, and then moved distally along the drainage conduit 112 away from the user (e.g., with the first bridge portion 752A and the second bridge portion 752B intact). FIGS. 9I-9J depicts the distal end 612B of the drainage conduit 112 being coupled to the collection reservoir 114. As shown in FIGS. 9I-9J, the collection reservoir 114 can be coupled to the side of a patient support structure (e.g., a hospital bed).

Although the applicator 118 includes the first lateral portion 318A, 618A and the second lateral portion 318B, 618B in FIGS. 3A-9J, the applicator 118 can have a different configuration in other examples. FIGS. 10A-13B depict aspects of the user interface 116 and/or the applicator 118 according to some other examples.

FIGS. 10A-10B depict a user interface 1016 for an implementation of the user interface 116 according to another example. As shown in FIG. 10A-10B, the user interface 1016 can include an adhesive sheet 1020, a release liner 1060, and an aperture 1046 in the adhesive sheet 1020. The adhesive sheet 1020 is substantially similar or identical to the adhesive sheet 120 described above, except the adhesive sheet 1020 in FIGS. 10A-10B can have a different shape. For example, in FIGS. 10A-10B, the adhesive sheet 1020 can include a plurality of arms that extend outwardly from a central portion. The central portion of the adhesive sheet 1020 can define the aperture 1046.

Additionally, the user interface 1016 includes a sacral pressure pad 1068. The sacral pressure pad 1068 can extend from a top edge of the adhesive sheet 1020 such that the sacral pressure pad 1068 is configured to be located adjacent to a sacrum of a user when the adhesive sheet 120 is coupled to the skin of the user with the aperture 1046 aligned with the anus of the user. The sacral pressure pad 1068 can have a thickness and a pliability that assists in reducing a pressure on the sacrum when the sacral pressure pad 1068 is positioned between the sacrum of the user and a support surface (e.g., a hospital bed and/or a wheel chair).

In some examples, the sacral pressure pad 1068 can include an adhesive that that is configured to couple the sacral pressure pad 1068 to the sacrum of the user. In such examples, the release liner 1060 can also include a sacral portion that covers the adhesive on the sacral pressure pad 1068 prior to adhering the sacral pressure pad 1068 to the user.

Similar to the first and second release liners described above, the sacral portion of the release liner 1060 can include a first portion 1060A and a second portion 1060B. The first portion 1060A can cover the adhesive on the sacral pressure pad 1068 to inhibit the adhesive prematurely or inadvertently adhering to an object prior to application of the user interface 116 to the user. The second portion 1060B can have a first end that is coupled to the first portion 1060A at an inner portion of the sacral pressure pad 1068 (e.g., at an end closest to the adhesive sheet 1020), and a second end that is separate from the first portion 1060A at an outer portion of the sacral pressure pad 1068 (e.g., at an end farthest away from the adhesive sheet 1020). In this arrangement, a practitioner can grasp the second end of the second portion 1060B and pull outwardly away from the user and the adhesive sheet 1020 to separate the first portion 1060A of the release liner 1060 from the adhesive on the sacral pressure pad 1068. In this way, the release liner 1060 can be progressively expose the adhesive on the sacral pressure pad 1068 in a direction from the adhesive sheet 1030 towards the peripheral edge of the user interface 116. This can help to improve coupling the adhesive to the sacrum.

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FIGS. 11A-11B depict a user interface 1116 for an implementation of the user interface 116 according to another example. As shown in FIG. 11A-11B, the user interface 1116 can include an adhesive sheet 1120, a release liner 1160, an aperture 1146 in the adhesive sheet 1120, and a sacral pressure pad 1168. However, in this example, the sacral pressure pad 1168 includes a plurality of slits 1169. The slits 1169 in the sacral pressure pad 1168 can help to splay the sacral pressure pad 1168 over the sacrum of the user, and can assist in removing the sacral pressure pad 1168 from the user. These functions can be further enhanced by arranging the slits 1169 at a diagonal orientation relative to a longitudinal axis of the sacral pressure pad 1168.

FIGS. 12A-12C depict a user interface assembly 1210 including a user interface 1216 and an applicator 1218 for an implementation of the user interface 116 and the applicator 118 and according to another example. In FIGS. 12A-12C, the user interface 1216 is disposed within an aperture 1219 in the applicator 1218 while coupling the user interface 1216 to the user, and the applicator 1218 and the user interface 1216 are configured to decouple from each other after coupling the user interface 1216 to the user.

In this example, the user interface 1216 defines an aperture 1246 that is configured to communicate with the lumen of the drainage tube 112 described above. As shown in FIG. 12B, the user interface 1216 can also include an adhesive sheet 1220 and a release liner 1260, as described above.

FIG. 12A and FIG. 12C depict the user interface assembly 1210 in a first configuration in which the user interface 1216 is received in the aperture 1219 of the applicator 1218. As shown in FIG. 12C, the user interface assembly 1210 is configured to be bent and/or folded along an axis extending through the user interface 1216 without the user interface 1216 decoupling from the applicator 1218. In this first configuration, an operator can hold the applicator 1218 while coupling the user interface 1216 to the user in a manner similar to that described above.

FIG. 12B depicts the user interface assembly 1210 in a second configuration in which the user interface 1216 is decoupled from the applicator 1218. In an example, the adhesive 1210 can have a first breakaway force that defines an amount of force that is required to remove the user interface 1216 from the skin of the user, and the user interface assembly 1210 can have a second breakaway force that defines an amount of force that is required to decouple the applicator 1218 from the user interface 1216 along an interface between the applicator 1218 and the user interface 1216 (e.g., along a circumference of the aperture 1219). The first breakaway force can be greater than the second breakaway force. In this arrangement, when the user interface 1216 is coupled to the skin of the user, the operator can decouple and remove the applicator 1218 by pulling the applicator 1218 away from the user interface 1216 with a force that is (i) greater than the second breakaway force and (ii) less than the first breakaway force.

FIGS. 13A-13B depict a user interface assembly 1310 including a user interface 1316 and an applicator 1318 for an implementation of the user interface 116 and the applicator 118 and according to another example. The user interface assembly 1310 is substantially similar to the user interface assembly 1210 of FIGS. 12A-12C, except the user interface assembly 1310 includes a user interface 1316 having a plurality of arms extending from a central ring, which defines an aperture 1346 for communicating with the lumen of the drainage conduit 112.

Similar to the user interface assembly 1210 of FIGS. 12A-12C, the user interface 1316 is disposed within an

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aperture 1319 in the applicator 1318 while coupling the user interface 1316 to the user, and the applicator 1318 and the user interface 1316 are configured to decouple from each other after coupling the user interface 1316 to the user. However, the user interface assembly 1310 of FIGS. 13A-13B differs from the user interface assembly 1210 in that the arms of the user interface 1316 extend beyond the aperture 1346 and are coupled to the distal side of the applicator 1318 when in the first configuration. After coupling an adhesive sheet 1320 on the central ring of the user interface 1316 to the skin of a user, the applicator 1318 can be pulled away from the user interface 1316 with a force between the first breakaway force and the second breakaway force described above to decouple the applicator 1318 from the user interface 1316. In this example, while decoupling the applicator 1318 from the user interface 1316, the arms can pass through the aperture 1319 of the applicator 1318.

FIGS. 14-20 depict additional views of the applicator 118 shown in FIGS. 6-9G according to an example.

The description of the different advantageous arrangements has been presented for purposes of illustration and description, and is not intended to be exhaustive or limited to the embodiments in the form disclosed. Many modifications and variations will be apparent to those of ordinary skill in the art. Further, different advantageous embodiments may describe different advantages as compared to other advantageous embodiments. The embodiment or embodiments selected are chosen and described in order to explain the principles of the embodiments, the practical application, and to enable others of ordinary skill in the art to understand the disclosure for various embodiments with various modifications as are suited to the particular use contemplated.

What is claimed is:

1. A method of using a fecal collection system, comprising:
 - positioning a user interface assembly at an anus of a user, wherein the user interface assembly comprises a user interface and an applicator, wherein the user interface comprises an adhesive sheet;
 - removing a first release liner from a first half of the adhesive sheet and removing a second release liner from a second half of the adhesive sheet, wherein the first release liner comprises a first portion and a second portion, wherein the first portion of the first release liner covers the first half of the adhesive sheet, wherein the second portion of the first release liner has a first end that is coupled to the first portion of the first release liner at an inner portion of the user interface and a second end that is separate from the first portion of the first release liner at an outer portion of the user interface,
 - wherein the second release liner comprises a first portion and a second portion, wherein the first portion of the second release liner covers the second half of the adhesive sheet, wherein the second portion of the second release liner has a first end that is coupled to the first portion of the second release liner at an inner portion of the user interface and a second end that is separate from the first portion of the second release liner at an outer portion of the user interface,
 - wherein removing the first release liner from the first half of the adhesive sheet comprises pulling the second end of the second portion of the first release liner outwardly away from the user to separate the first portion of the first release liner from the adhesive sheet, and

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wherein removing the second release liner from the second half of the adhesive sheet comprises pulling the second end of the second portion of the second release liner outwardly away from the user to separate the first portion of the second release liner from the adhesive sheet;

coupling the user interface to skin of the user by using the applicator to press the user interface against the skin of the user, wherein coupling the user interface to skin of the user comprises coupling an adhesive sheet of the user interface to the skin of the user; and

after coupling the user interface to the skin of the user, removing the applicator from the user interface.

2. The method of claim 1, wherein coupling the user interface to skin of the user by using the applicator to press the user interface against the skin of the user comprises aligning an alignment indicator on the applicator with the anus,

wherein the alignment indicator indicates a position of an aperture in the user interface, and

wherein the alignment indicator comprises a first line that extends on the applicator from a top of the aperture to a peripheral edge of an adhesive sheet, and a second line that extends on the applicator from a bottom of the aperture to the peripheral edge of the adhesive sheet.

3. The method of claim 1, wherein a proximal end of a drainage conduit is coupled to the user interface at a location that is offset below a center of the user interface.

4. The method of claim 1, wherein the applicator comprises a first tab on a peripheral edge of the first lateral portion and a second tab on a peripheral edge of the second lateral portion, wherein the first tab and the second tab extend laterally past a peripheral edge of the user interface such that the first tab and the second tab facilitate gripping and handling of the applicator when positioning the user interface assembly between a user's buttocks.

5. The method of claim 1, wherein coupling the user interface to the skin of the user by using the applicator to press the user interface against the skin of the user comprises:

hingedly moving, about a hinge portion of the applicator, a first lateral portion of the applicator and a second lateral portion of the applicator relative to each other to press the user interface against the skin of the user.

6. The method of claim 5, wherein the applicator further comprises a slit extending along the hinge portion between the first lateral portion and the second lateral portion of the applicator.

7. The method of claim 5, wherein coupling the user interface to skin of the user by using the applicator to press the user interface against the skin of the user comprises holding the user interface and the applicator in a single hand while the user interface and the applicator are in a folded state such that the first lateral portion and the second lateral portion are folded about the hinge portion, and the user interface is positioned externally to the applicator.

8. The method of claim 7, wherein the applicator has a size that is larger than the user interface such that the user

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interface can be gripped when the user interface and the applicator are in the folded state.

9. The method of claim 5, wherein removing the applicator from the user interface comprises decoupling the first lateral portion and the second lateral portion from the user interface.

10. The method of claim 9, wherein decoupling the first lateral portion and the second lateral portion from the user interface is performed while the user interface and the applicator are in an extended state.

11. The method of claim 5, wherein the hinge portion comprises a first bridge portion and a second bridge portion, and

wherein the first lateral portion and the second lateral portion are coupled to each other only at the first bridge portion and the second bridge portion.

12. The method of claim 11, wherein the first bridge portion extends between (i) an aperture of the user interface and (ii) a slit extending along the hinge portion between the first lateral portion and the second lateral portion of the applicator.

13. The method claim 11, wherein the second bridge portion extends between (i) an aperture of the user interface and (ii) a peripheral edge of the applicator at the hinge portion.

14. The method of claim 11, wherein removing the applicator from the user interface comprises decoupling the first lateral portion and the second lateral portion from each other at at least one of the first bridge portion and the second bridge portion.

15. The method of claim 14, wherein decoupling the first lateral portion and the second lateral portion from each other comprises tearing the first bridge portion.

16. The method of claim 1, further comprising coupling a collection reservoir to a distal end of a drainage conduit, wherein a proximal end of the drainage conduit is coupled to a distal side of the user interface, wherein the drainage conduit defines a lumen configured to guide feces from the proximal end to the distal end.

17. The method of claim 16, wherein the fecal collection system further comprises a first one-way valve in the lumen defined by the drainage conduit, wherein the first one-way valve is configured to allow feces to flow in a direction from the proximal end to the distal end and inhibit feces from flowing in a direction from the distal end to the proximal end.

18. The method of claim 16, wherein the fecal collection system further comprises a second one-way valve that is configured to allow feces to flow from the drainage conduit to the collection reservoir and inhibit feces from flowing from the collection reservoir to the drainage conduit.

19. The method of claim 16, further comprising milking feces in the drainage conduit toward the collection reservoir.

20. The method of claim 16, further comprising coupling the drainage conduit to the user interface.

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